DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

(PARAMEDIC, SCT, APRU)

SUBJECT: **CONTROLLED DRUGS CARRIED ON ALS SCT AND APRU UNITS** REFERENCE NO. 702

PURPOSE: To ensure accountability for all controlled drugs issued to Advanced Life Support (ALS), Specialty Care Transport (SCT), and Advanced Practitioner Response (APRU) units.

AUTHORITY: Health and Safety Code, Chapter 5, 1797.220 and 1798
California Business and Professions Code, Section 4005 and 4119 .01, 4034.5
Department of Justice, DEA Regulations, Title 21, Code of Federal Regulations, Section 1300-END
Controlled Substances Act, 21 USC 801-890

DEFINITIONS:

Provider Agency Medical Director: A physician who has been appointed by an approved EMS Provider Agency, meets the criteria outlined in Ref. No. 411, 9-1-1 Provider Agency Medical Director or Ref. No. 420, Private Ambulance Operator Medical Director, is approved by the EMS Agency Medical Director, and agrees to procure controlled drugs under their DEA Registrant, and provide oversight of all medications utilized by EMTs, paramedics, SCT personnel and advanced practice providers, including controlled medications.

Automated Drug Delivery System (ADDS): A mechanical pharmaceutical storage and dispensing system that utilizes computer-controlled tracking of medications.

PRINCIPLES:

1. Effective controls and procedures are essential to guard against theft and diversion of controlled drugs due to the risks associated with mishandling of these drugs.

2. Controlled drugs will be restocked and stored only in full amounts. Unused, partial doses shall be discarded appropriately.

3. Providers shall carry only one narcotic analgesic on the ALS units. Provider Agency Medical Directors who intend to carry Fentanyl, in lieu of morphine sulfate, shall contact the EMS Agency's Medical Director for approval.

4. Implementation of a paperless (electronic tracking) Daily Controlled Inventory Form requires the prior approval of the EMS Agency.

5. Provider agencies may utilize an ADDS for storage and dispensing of controlled drugs.

6. It is the responsibility of the Provider Agency Medical Director to be knowledgeable of the Federal, State, and local regulations that govern controlled drugs.

APPROVED: Richard Tadeo
Director, EMS Agency

Medical Director, EMS Agency

7. Provider Agency Medical Director shall be involved in the development and approval of all medically related policies and/or procedures, including controlled drugs, quality improvement and medical dispatch programs.

8. Formulation of controlled drugs shall adhere to Ref. No. 1309, Color Code Drug Dosages and stocked in single patient use unit dosages.

9. Minimum quantities of the following approved controlled drugs carried on approved ALS, SCT and APRU Units shall be sufficient to treat a minimum of two (2) patients as identified in EMS Agency approved unit inventory policies with maximum inventory quantities identified within each approved EMS Providers controlled drug policy.
   a. Fentanyl
   b. Morphine sulfate
   c. Midazolam

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POLICY:

I. Provider Agencies shall obtain Controlled Drugs through its appointed Medical Director.

II. Controlled Drug Program:

   A. Provider agencies shall maintain a controlled drug program in accordance with the policies and procedures set forth by the EMS Agency.

   B. Provider agencies shall have a policy(s) in place, approved by the EMS Agency, which address, at minimum, the following:

      1. Description of the methodology (safe, etc.) utilized to store controlled drugs in locations other than the ALS unit(s).

      2. Description of the procedure used to track inventory control (restocking and dispensing) of controlled drugs.

      3. Description of procedure for restocking controlled drugs on an ALS unit(s).

      4. Identify the level of personnel who have access to the controlled drug storage area.

III. Controlled Drug Security:

   A. Controlled drug security requirements apply to all provider agencies.

   B. Paramedics assigned to an ALS unit, Registered Nurses (RN) assigned to a SCT unit, and Advanced Practitioners assigned to an APRU shall be responsible for maintaining the correct controlled drug inventory and security of the drug keys (or confidentiality of the keypad/padlock combination) for their assigned unit at all times.

   C. Controlled drugs shall not be stored in any location other than the EMS Agency approved primary storage safe, on ALS, SCT or APRU unit(s) or ADDS. Alternate storage areas shall be reviewed and authorized by the EMS Agency prior to implementation. The authorization process requires EMS Agency

inspection of the storage facility and approval of the provider agency internal policy specifying the location, security, access, and procedure for obtaining drugs from the alternate controlled drug locations. If utilizing an electronic system to track controlled substances, there must be an electronic entry by two authorized personnel anytime the secured storage container is accessed, in addition to a physical count of the inventory conducted.

D. Controlled drugs shall be secured on the ALS, SCT or APRU unit(s) under double lock. Provider agencies that have more than one approved ALS/SCT/APRU unit must have unique double locking mechanisms for each ALS/SCT/APRU unit.

E. Daily Inventory Procedures of controlled drugs on an ALS, SCT or APRU unit:

1. Controlled drugs shall be inventoried by physical count by two paramedics for ALS; two RNs or one paramedic and one RN for SCT; or one advanced practitioner and one RN or paramedic for APRU, at least daily, and anytime there is a change in personnel.

2. The key to access-controlled drugs shall be in the custody of the individual who performed the inventory.

3. The Daily Controlled Drug Inventory Form, Ref. No. 702.2 or its equivalent, shall be co-signed with the names of the relinquishing and the receiving paramedic or RN or advanced practitioner, as applicable. Entries shall be in blue or black ink only, or electronic equivalent.

4. Errors shall be corrected by drawing a single line through the incorrect wording; the writing underneath the single line must remain readable. The individual making the change should initial adjacent to their correction. Correction fluid or other erasure material is not permitted.

5. The Daily Controlled Drug Inventory Form, Ref. No. 702.2 or its equivalent, must be maintained by the provider agency for a minimum of three years. An entry shall be made on this form for each of the following situations:

    a. Change of shift.

    b. Any change to the controlled drug inventory.

    c. Any time there is a change of responsible personnel.

    d. Providers authorized to participate in the 1:1 Staffing Program for Interfacility Transports are required to inventory controlled drugs at the end of the specified shift, when two paramedics are available to count and co-sign for the drugs.

F. Electronic (paperless) Daily Inventory Procedures of Controlled drugs on an ALS, SCT or APRU unit

1. To implement an electronic tracking system for daily inventory, the provider agency shall choose a system that meets the following requirements

    a. The system must fulfill all requirements listed in section III-C and E-5 above and possess the ability to produce a printed or electronic daily drug inventory report by, at minimum, calendar month.

    b. Electronic documentation must verify the identity of the receiving and relinquishing party at change of shift or change of responsible personnel, when medications are used, and at the time of restocking.

    c. Access to the system shall require at minimum, an employee identification number and a personal identification number. Biometric (fingerprint, retinal scan, etc.) may be used in addition to or in lieu of the above requirements and is strongly encouraged.

    d. The system must comply with all federal, state, and local regulations/policies.

    e. The provider agency must have the ability to revert to a paper system in the event of temporary or long-term downtime of the electronic system.

G. Lost or Missing Controlled Drug

a. Any lost, missing, or discrepancy of controlled drugs shall be reported by the following business day (telephone notification is acceptable) to the paramedic coordinator, the EMS Agency, and the authorizing Provider Agency Medical Director. Verbal notification must be followed by a written report within three business days including completion of Ref. No. 702.3, Lost/Missing Controlled Drug Reporting Form.

b. A police report must be completed for any missing, lost, or suspected diversion of a controlled drug.

c. Any significant loss, breakage, or discrepancy in the count requires notification to the DEA, utilizing DEA Form 106 or electronically via the DEA web site, within one business day of discovery.

d. Any loss shall initiate supervisory review at the involved provider agency. If a provider agency's internal investigation into a controlled drug loss exceeds 30 days, the provider shall submit a status update to the Provider Agency Medical Director and the EMS Agency at the 30th day.

H. Disposal of controlled drugs

The provider agency shall dispose of expired controlled drugs through a DEA licensed pharmaceutical reverse distributor and/or by implementing the

guidelines outlined in the Code of Federal Regulations, 1317, Disposal of Controlled Substance by Registrants.

IV. Record Keeping:

A. All controlled drugs issued to a provider agency must be accounted for. The provider agency shall retain a copy (printed or electronic) of the Patient Care Record (PCR) for each patient to whom a controlled drug was administered and maintain it with any completed controlled drug inventory and report forms, drug orders, invoices, or other associated documentation in a separate file for a minimum of three years.

B. If the total amount of the drug is not administered, the remaining amount shall be wasted at the receiving facility, or in a container approved for destruction of controlled drugs.

1. Document the amount of wasted drugs (partial or whole) in the "Drug Waste/Witness" section of the PCR.

2. Obtain the signature of the witness who observed the disposal of the remaining solution and print the witness' name on the PCR. A witness shall include a registered nurse, physician, pharmacist, or if none of these options are available, a second paramedic with a current California paramedic license.

C. Controlled drug inventories and logs are subject to inspection by the EMS Agency, the issuing pharmacy, the California Board of Pharmacy, and agents of the Bureau of Narcotic Enforcement Administration of the Department of Justice, and the Federal Drug Enforcement Administration.

V. ADDS

Provider agencies that use ADDS for storage and dispensing of controlled drugs are responsible for ensuring compliance with State and Federal regulations as it relates to implementing and maintaining the system.

CROSS REFERENCE:

Prehospital Care Manual:

Ref. No. 214, **Base Hospital and Provider Agency Reporting Responsibilities**
Ref. No. 411, **9-1-1 Provider Agency Medical Director**
Ref. No. 420, **Private Ambulance Operator Medical Director**
Ref. No. 606, **Documentation of Prehospital Care**
Ref. No. 607, **Electronic Submission of Prehospital Data**
Ref. No. 701, **Supply and Resupply of Designated EMS Provider Units/Vehicles**
Ref. No. 702.1, **Provider Agency Medical Director Notification of Controlled Drug Program Implementation**
Ref. No. 702.2, **Daily Controlled Drug Inventory Form**
Ref. No. 702.3, **Lost / Missing Controlled Drug Reporting Form**
Ref. No. 702.4, **Monthly Drug Storage Inspection Form**
Ref. No. 703, **ALS Unit Inventory**

Ref. No. 703.1, **Private Provider Interfacility Transfer ALS Unit Inventory**
Ref. No. 706, **ALS EMS Aircraft Inventory**
Ref. No. 712, **Nurse Staffed Specialty Care Transport Unit Inventory**
Ref. No. 719, **Fireline Emergency Medical Technician-Paramedic (FEMP) Inventory**