DEPARTMENT OF HEALTH SERVICES
COUNTY OF LOS ANGELES

SUBJECT: **SUPPLY AND RESUPPLY OF DESIGNATED PROVIDER UNITS/VEHICLES** (ALL PROVIDER AGENCIES) REFERENCE NO. 701

PURPOSE: To provide a policy for provider agencies (public and private) to procure, store, and distribute medical supplies and pharmaceuticals identified in the Unit Inventory that require specific physician authorization.

AUTHORITY: California Health and Safety Code, Division 10, Uniform Controlled Substances Act
California Health and Safety Code, Division 2.5, Chapter 5, Section 1798.
California Code of Regulations, Title 22, Chapter 3.3, Article 6, Section 100096.01.
Code of Federal Regulations, Title 21, Section 801.109.

DEFINITION:

Restricted Drugs and Devices: Drugs and devices bearing the symbol statement "Rx Only"; or the statement, "Caution, federal law prohibits dispensing without prescription"; or "Federal law restricts this device to sale by or on the order of a physician," or words of similar import.

POLICY:

I. Responsibilities of the Provider Agency

A. Each provider agency shall have a mechanism to procure, store, track utilization and distribute its own restricted drugs and devices under the license and supervision of a physician who meets the requirements specified in Ref. No. 411, Provider Agency Medical Director or Ref. No. 420, Private Ambulance Operator Medical Director.

B. Provider agency shall furnish the EMS Agency with a completed Ref. No. 701.1, Physician Confirmation of Agreement to Purchase Drugs and Medical Supplies indicating that the respective physician will assume responsibility for providing medical authorization for procuring restricted drugs and devices.

C. Mechanisms of procurement may include the following:

1. Procurement of restricted drugs and devices from a hospital that determines it has the legal authority to resell pharmaceuticals and supplies to a provider agency.

2. Procurement of restricted drugs and devices through another legally authorized source, including but not limited to, a pharmaceutical distributor or wholesaler.

D. Each provider agency shall have policies and procedures, reviewed, approved,

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and signed by the provider agency Medical Director, in place for the procurement, transport, storage, distribution, and disposal of restricted drugs and devices. These policies shall include, but are not limited to, the following:

1. Identification (by title) of individuals responsible for procurement and distribution.

2. A determination of reasonable quantities of supplies and pharmaceuticals that must be maintained to resupply units between deliveries by distributor to prevent or reduce the possibility of short supply from routine use, expiration, or during a regional/nation-wide shortage. Routine order amounts should be based on historical use data and other internal considerations.

3. Maintenance of copies of all drug orders, invoices, and logs associated with restricted drugs and devices for a minimum of three years.

4. Procedures for completing a monthly inventory, which includes:

    a. Ensuring medications are stored in original packaging;

    b. Checking medications for expiration dates, rotating stock for use prior to expiration, and exchanging expired medications;

    c. Proper disposing of expired medications that cannot be exchanged;

    d. Accounting for restricted drugs and devices in stock and/or distributed to ALS units and other transport units; and

    e. Returning medications to the pharmaceutical distributor if notified of a recall.

5. Storage of drugs (other than those carried on the unit itself) that complies with the following:

    a. Drugs must be stored in a locked cabinet or storage area.

    b. Drugs may not be stored on the floor (Storage of drugs on pallets is acceptable).

    c. Antiseptics and disinfectants must be stored separately from medications.

    d. Flammable substances, e.g., alcohol, must be stored in accordance with local fire codes.

    e. Storage area is maintained within a temperature range that will maintain the integrity, stability, and effectiveness of drugs.

6. A mechanism for procuring, storing, distributing, and accounting for controlled drugs that is consistent with the requirements outlined in Ref.

No. 702, Controlled Drugs Carried on ALS and SCT Units.

II. Pharmaceutical Shortages

A. Notification

1. Pharmaceutical recalls, shortages and other pharmaceutical-related concerns are identified through notifications from:

   a. The Food and Drug Administration (FDA)

   b. Provider agencies

2. Once notification is received, FDA is contacted to verify report and retrieve an expected recovery date.

3. If notification content from the FDA is expected to impact the Los Angeles County (LAC) EMS System, all ALS providers will be formally notified by the EMS Agency's Medical Director.

B. Mitigation Strategies

Mitigation strategies are identified in two categories as follows: 1. Those that can be implemented by the provider agency simultaneous with written notification to the LAC EMS Agency Medical Director, and 2. those that require prior approval of the LAC EMS Agency Medical Director prior to implementation.

1. Mitigation strategies which can be implemented by the provider agency with notification of the LAC EMS Agency Medical Director.

   a. Inventory Reduction:

      i. Provider agency may redistribute its current pharmaceutical inventory amongst its own units, from low volume to high volume utilizers.

      ii. The Medical Director of the provider agency may temporarily reduce the minimum inventory par levels.

      iii. Provider agencies that are low volume utilizers may redistribute a portion of its current inventory to other provider agencies that are high volume utilizers, with the exception of controlled substances.

   b. Provider agencies should attempt procurement from other pharmaceutical vendor resources.

   c. The provider agency may contact the LAC EMS Agency to obtain approval to receive pharmaceuticals from the disaster preparedness pharmaceutical cache.

   d. Use of expired medications as per published FDA extensions.

2. Mitigation strategies that require LA EMS Agency Medical Director approval prior to implementation:

   a. Change in opioid medication from what has previously been approved (i.e., change from morphine to fentanyl).

   b. Dilution of a medication to achieve the desired formulation (e.g., epinephrine 1mg/mL to achieve epinephrine 0.1mg/mL).

   c. Change in formulation of a medication that is not on the LAC EMS Agency approved list of formulations (Ref. MCG 1309).

   d. Approval for extension of use past expiration dates for medications not on the FDA extension list.

C. Recovery Phase

Once it has been identified that the current pharmaceutical shortage has resolved and provider agencies have received back-ordered medications, the following shall take place:

1. All units shall return to the minimum inventory amounts, as outlined in appropriate unit inventory lists.

2. Pharmaceuticals acquired from the EMS Agency or other provider agencies are to be equally replenished by the acquiring agency.

CROSS REFERENCES:

Prehospital Care Manual:
Ref. No. 411, **Provider Agency Medical Advisor**
Ref. No. 420**, Private Ambulance Operator Medical Director**
Ref. No. 702, **Controlled Drugs Carried on ALS Units**
Ref. No. 703, **ALS Unit Inventory**
Ref. No. 703.1 **Private Provider Interfacility Transfer ALS Unit Inventory**
Ref. No. 704, **Assessment Unit Inventory**
Ref. No. 706**, ALS EMS Aircraft Inventory**
Ref. No. 710, **Basic Life Support Ambulance Equipment**
Ref. No. 712**, Nurse Staffed Specialty Care Transport Unity Inventory**
Ref. No. 713, **Respiratory Care Practitioner Staffed Specialty Care Transport Unit Inventory**
Ref. No. 719, **Fireline Emergency Medical Technician Paramedic (FEMP) Inventory**