

CHECK LIST FOR CONTROLLED SUBSTANCE PLAN*

Each ALS provider shall develop a Controlled Substance Plan (CSP), including Morphine Sulfate, even though your service may not plan on carrying Morphine Sulfate. The CSP will describe, in detail, how the provider will obtain initial stock, securely transport, document use, waste, and restock, and, if necessary, maintain a secure onsite lock-up of Morphine. While CSPs may vary in structure, each must consist of the following elements:

Specific documentation forms and procedures for each of the following:

- _____ Morphine Security:
 - Each cartridge/syringe shall have a tamper-proof seal.
 - Secured together in a keyed-lock container.
 - Containers shall be secured in either a cabinet inside the ALS vehicle, or storage cabinet inside a key-locked storage room.
- _____ The method of DEA Registration to be used (see section IV).
- _____ Obtaining an initial stock for each ALS vehicle.
 - Must be delivered to the ALS vehicle by a Provider supervisor.
 - Each drug box must be numbered.
 - Maximum amount of Morphine (total of 20mg per box).
- _____ Restock following administration in the field.
- _____ Restock following loss or breakage of container.
- _____ Methods of testing those who are suspected of abusing/diverting drugs.
- _____ An internal orientation for new employees.
- _____ An internal on-going training program.
- _____ A quality improvement program.
- _____ A designated CSP oversight coordinator.
- _____ Off-Line Medical Director's approval (signed).

Each ALS provider shall submit a Controlled Substance Plan to the OEMST for approval prior to applying to the DEA.

Note: This is merely a checklist intended to prompt the authors of a provider's CSP of the requirements for the initial and continuous acquisition of Morphine. For details, please consult the Controlled Substance Guidelines that accompany this checklist.

***The Check List for the Controlled Substance Plan is not applicable for services that provide IV Fluids only.**

CONTROLLED SUBSTANCES GUIDELINES FOR ALS SERVICES

Authority to obtain and use controlled substances is regulated by the Controlled Substances Act (Public Law 91-513) and other Federal and State laws, regulations and guidelines. Ambulance services are licensed and regulated by the Drug Enforcement Administration (DEA), and the Alabama Department of Public Health, Office of Emergency Medical Services and Trauma.

a. CONTROLLED DRUGS

Controlled substances are classified into five Schedules according to their abuse potential: Schedule I, which are highly abused and have no approved medical use, through Schedule V, which have minimum abuse potential.

Although all controlled substances are included, those most commonly used by ambulance services are, Morphine, Diazepam (Valium), and Lorazepam (Ativan).

b. POLICY AND PROCEDURE/CLINICAL PROTOCOL

A complete controlled substance policy and procedure must be provided and approved by the Alabama Department of Public Health, OEMST which meets the standards of these guidelines. All controlled substances to be utilized by the ambulance service must be included in the provider's clinical protocol, and the strengths and amounts of each drug must be listed.

c. DEA REGISTRATION

DEA does not register ambulance services or vehicles. DEA allows an ambulance service to obtain and transport controlled substances under one of two authorities, hospital registration or practitioner registration:

1. Hospital Registration

- i. If the ambulance service is owned/operated by a hospital registered with the DEA, controlled substances may be supplied to the emergency vehicle under the registration of the hospital.
- ii. A privately-owned ambulance service, or one which is owned by a municipality, may enter a formal written contractual agreement with one specific hospital to supply the emergency vehicle with controlled substances. Again, the controlled substances will be provided under the registration of the contracted hospital. A copy of the written contractual agreement between the ambulance service and the hospital must be submitted to the New Orleans DEA Resident Office.

2. Practitioner Registration (Physician)

- i. An ambulance service may obtain controlled substances through the services of a consulting practitioner. The practitioner must be registered with DEA at the central office location of the owner/operator of the emergency vehicle. When applying for this registration, the name of the ambulance service will appear on the first line of the DEA-224, Application for Registration. The consulting practitioner's name will appear on the second line, and the address will be that of the central office location of the ambulance service. The practitioner must sign the application.
- ii. A hospital must elect to delegate to a practitioner the responsibility for the controlled substances stored in an emergency vehicle by registering the practitioner with DEA at the hospital location. To become registered, the hospital-designated practitioner must sign the application.

Revised: 5/17/07

To obtain Schedule II controlled substances for the emergency vehicle, the practitioner must order Schedule II controlled substances through the use of a DEA-222, Official Order Form, issued to the practitioner containing the registered name and address. Schedules III – V controlled substances may be obtained by the consulting practitioner through the use of a requisition form containing the registrant's name, address, and DEA number. The practitioner will **not** obtain controlled substances for the ambulance service through the use of a prescription.

The consulting or hospital-designated practitioner is responsible for all activities relating to controlled substance use, and the record keeping required by federal regulations.

The following information must be included with a photocopy of the application for registration:

- d. A letter from the consulting or hospital-designated practitioner stating acceptance of this position.
- e. Types and amounts of controlled substances.
- f. Security measures for controlled substances stored on ambulances and at base locations.
- g. Purchasing and return policies for controlled substances.

GENERAL RECORD KEEPING REQUIREMENTS

Controlled substance records should be written in ink. All records pertaining to the acquisition, handling, and disposition of controlled substances must be maintained at the registered location for at least two years. They must be separate from other records and must be readily retrievable.

A perpetual inventory format of record keeping should be kept at each location (base or ambulance) where controlled substances are stored, which documents all receipt and disposition transactions and shows a current inventory level of each controlled substance at all times. A biennial inventory in accordance with Title 21 Code of Federal Regulations Section 1304.13 is also required.

If any records (including unexecuted DEA-222, Official Order Forms) are stored at a location other than the registered location, DEA must be notified in writing. Executed Official Order Forms must be stored at the registered location, i.e., hospital pharmacy or central office location. If obtaining controlled substances through a hospital registration, the ambulance service must still maintain their own set of records for use of controlled substances.

h. PURCHASING

Controlled substances are usually procured for ambulance services through a hospital based pharmacy; however, they may also be obtained from an outside source. See Schedule III, IV & V below. They may only be obtained from a DEA registrant, and complete record keeping must be maintained.

DEA Official Order Forms must be used for any acquisition of a Schedule II controlled substance. Official Order Forms should be used according to their sequential numbers. Copy 3 must be maintained by the purchaser (registrant), and the date and amount received noted on the copy. Copies 1 and 2 are sent to the registered supplier (either a hospital pharmacy or an outside source). Order forms must be obtained through the New Orleans DEA Office.

Schedule III, IV & V controlled substances do not require Official Order Forms, however, all transactions must be recorded. In addition, you must go on-line to the Office of Diversion Control, under the DEA Website at www.deadiversion.usdoj.gov, for a ***Request to Modify*** in order to purchase any Schedule III, IV or V controlled substances from an outside source.

Follow the instructions under Diversion Programs found on the left side of the screen and pull up the Schedule Change Request (PDF version). Follow the instructions and complete this form prior to purchasing any Schedule III, IV or V controlled substances from an outside source. Remember, Morphine Sulfate is a Schedule II controlled substance and requires the DEA Form 222 for approval, and Diazepam (Valium) and Lorazepam (Ativan) are Schedule IV controlled substances, which require your service to follow the above Schedule Change Request procedure for purchase from an outside source.

A physician's prescription cannot be used to obtain stock supplies of controlled substances for the ambulance service, since a prescription can only be legally written for a patient. A prescription cannot be used to "replace" a dose to the ambulance service by the hospital for a dose which was used on a patient being brought to the hospital, because the dose being provided is for stock replacement and not for administration to the patient. A purchase order or other request document should be used for purchase or replacement transactions, and complete receiving documentation maintained.

Invoices and/or other receiving records must be maintained for all controlled substances and must include the name, address, registration number of the supplier, and the name and amount of the controlled substance received, including the date received. A biennial inventory is required in accordance with DEA regulations.

i. STORAGE/SECURITY

Controlled substances must be stored in a securely locked, substantially constructed cabinet which is permanently attached to a wall or floor of a secured room. The cabinet should not be labeled to identify its contents. Controlled substances inside this cabinet should also be in a separate box sealed with a combination or keyed lock.

Controlled substances stored on an ALS unit will be maintained in a secured drug box (lockable or in a locked cabinet) with the additional ALS medications. Controlled substances will be locked in a separate (unlabeled) container inside the drug box. Access to controlled substances should be limited by policy to only persons authorized to administer them. Only credentialed Paramedics should have access to the controlled substances.

When there is concern about physical security of base supplies of controlled substances at a registered location, these supplies may be stored at a more secure location such as a hospital or central office. A separate registration is not necessary, but DEA must be notified and certain restrictions apply.

j. INVENTORIES/AUDITS

A biennial inventory (every two years) is required for all controlled substances and must be taken on a specified date. Audits of base supplies should be done on a periodic basis (e.g., daily or weekly) depending on the number of persons with access and frequency of use.

Audits of supplies in the ambulance should be done at each shift change by oncoming and off going personnel. If tamper proof seals are used on the immediate container, the seal number may be compared and recorded rather than doing a visual count. The seal should be checked to see that it is locked. The seal should be removed and a visual count done at least monthly on or very near the end of the month.

All audits should show the date, time, and amount of controlled substances and two signatures that are preferably recorded on a perpetual inventory form with other transactions on each ambulance. Key transfer or accountability should be part of this documentation.

Any discrepancies found should be reconciled before the staff from the current shift leaves. If the discrepancy cannot be reconciled, the immediate supervisor should be notified and a written report prepared.

Purchasing and distribution records should be reconciled periodically, and the hospital medical director or registered practitioner should review the inventory and record keeping periodically.

k. ADMINISTRATION/WASTE

When a controlled substance is administered, the following information should be recorded on the ambulance perpetual inventory record: patient name, date, time, controlled substance name and strength, dose, ordering physician's name, PCR number, and paramedic signature. The patient name and address must appear on the PCR. If the ordering physician is at the destination, the physician's signature should be obtained on the PCR.

When a partial dose must be destroyed at the time of administration, the waste amount must be visually witnessed, preferably by a paramedic, nurse, or physician. Also, a responsible patient care employee may witness the destruction. The date, time, controlled substance name, amount, reason for destruction, and two signatures must be recorded.

Patient contaminated doses must be destroyed and witnessed by the same procedure. The unit partner may not be the witness to the disposal or wasting of any controlled substance.

I. OTHER DISPOSITION

When controlled substances are transferred to or from the base supply and the ambulance, or between ambulances, proper documentation should be made on the records for each location. If controlled substances are transferred to a remote location, which has its own registration or to any other registrant (e.g., "trade-ins"), the name, address, and DEA registration number must be included in the record and Official Order Forms must be used for Schedule II controlled substances.

Damaged, non-patient contaminated, expired or other unwanted controlled substances may be disposed of by the DEA, the Board of Pharmacy, or Health-Related Boards. Any special requests should be directed to the DEA, New Orleans Office.

Some controlled substances may be returnable to the pharmacy. When this occurs, a complete record of the disposition must be made, including the pharmacy DEA registration number. The supplier will issue an Official Order Form for the return of Schedule II controlled substances.

m. LOSS REPORTING

Any theft or loss of controlled substances must be immediately reported to the Drug Enforcement Administration on a DEA Form 106, Report of Theft or Loss of Controlled Substances. Thefts should also be immediately reported to the local law enforcement agency.

n. INSPECTIONS

DEA Investigators, the Office of EMS & Trauma or their designee, and the supplying pharmacy are authorized to inspect all records, security, and procedures associated with controlled substances.

o. HOSPITAL-BASED SERVICES

Ambulance services based at hospitals, which are owned and operated by another entity, must comply with all previous guidelines.

Ambulance services which are owned, and operated by a hospital from the hospital location, do not require separate DEA registration. Policies and procedures for controlled substances should be developed with the hospital pharmacy and should be consistent with those in other patient care areas. Controlled substances may be transferred between the hospital pharmacy and ambulances with hospital record keeping procedures and without Official Order Forms or other receiving and disposition records. Ambulance services must be included in the biennial inventory as part of the hospital pharmacy's inventory requirement. Transactions with other registrants, disposal of unwanted controlled substances, and theft or loss reporting must be handled by the hospital pharmacy since the ambulance service is acting as an extension of the pharmacy.

Questions should be referred to the Drug Enforcement Administration, New Orleans Field Division, Three Lakeway Center, 3838 N. Causeway Blvd, Suite 1800, Metairie, LA 70002 Att: Special Agent Terry Boyle.