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PHARMACY SERVICES/DRUG CONTROL
EMS FREQUENTLY ASKED QUESTIONS
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What does the term "controlled substance" mean?

"Controlled substance" as defined means a drug, compound, mixture, preparation, or substance included in Schedule I, II, III, IV, or V. For a complete list of the controlled substances for the state of Arkansas click this link: **Arkansas Controlled Substance List**

What does the term "prescription drug" sometimes refered to as "dangerous drug" mean?

"Prescription drug," as defined means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian", or any similar restrictive statement. This includes medical grade oxygen and IV solutions.

What are the security requirements for the storage of dangerous drugs?

As defined in EMS rules (Page 62) Section XIV. C. Security:

1. The controlled substances storage area at the ambulance service's physical location shall be accessible only to specifically authorized employees.

2. The Licensee shall provide adequate security for all legend (prescription) drugs on-board all registered vehicles. Schedule II drugs have a separate requirement for security that also must be complied with by the licensee.

3. All controlled substances shall be stored under a mounted double lock security. All other prescription drugs shall be stored under a single lock security

**All dangerous drugs must be maintained in a clean and temperature-controlled environment.
An Example of a Common Security & Storage Practice:
A drug box, cabinet, drawer, etc. that contains prescription drugs which is secured with a tamper-evident numbered seal tab system or a lock system that has been approved by the Department. EMS organizations using a seal tab system must also maintain a complete and accurate tamper evident log book for each box, cabinet, drawer, etc. to document access and drug accountability.

Who is required to have a registration?

All licensed entities in Arkansas who want to conduct any activities with controlled substances, including purchasing, stocking, ordering, prescribing and administering, must first obtain approval from the Pharmacy Services and Drug Control Section and a federal DEA registration. No person or agency in Arkansas may conduct any controlled substance activity without the above.

Who can have access to controlled substances?

Only emergency medical technician-paramedics, registered nurses, physicians, and pharmacists who are associated with that EMS organization may have access to any controlled substances maintained by the EMS organization. Other persons employed by the EMS organization may have access to controlled substances only under the direct and immediate supervision of an emergency medical technician-paramedic, a registered nurse, or a physician in emergency situations.

What EMS personnel may administer dangerous drugs?

Administration of dangerous drugs by EMS personnel is limited to the scope of practice as defined by the EMS Rules and Regulations adopted by the Board of Health, for the individual's licensure level and protocols (within scope of practice) as established by the medical director of the Service. Please see EMS Rules and Regulation (page 38 - 41) Section VIII. B. Approved Emergency Medical Services Personnel Skills

What should you do with medications that have expired?

As defined in EMS Rules and Regulations Section XIV F. Surrender of Unwanted Controlled Substances:

All controlled substances no longer usable due to deterioration, expired dating, or no longer used by the service should:

1. Must be delivered in person or by registered mail or other means of shipment with return receipt and all completed copies of Report of Drugs Surrendered (Form PhA:DC-1) furnished by the Department of Health to: Office of Pharmacy Services and Drug Control, Arkansas Department of Health, 4815 West Markham Street Slot-25, Little Rock, AR 72205-3867, Contact number is 501-661-2325.

2. a DEA-41 form also needs to be filled out by the EMS Service and the Health Department official needs to sign the back of the form once the drugs have been destroyed. A copy of the completed DEA-41 needs to be stored with your other controlled substance records at the registered location.

3. May be destroyed only by authorized agents of the Arkansas Department of Health.

Is an EMS Service required to have a separate DEA registration for every physcial location where controlled substances are stored.

Yes. Each location in which controlled substances are stored must have a separate registration. This means maintaining multiple registrations. Each separate site must have their own separate safe and set of records. Since each site will have a different Medication Approval from the Pharmacy Services and Drug Control and DEA number, each site will have its own receipt records, annual inventory, administration records, and wastage records. These records must be maintained and stored at each of the individual registered sites. This means if your service has three separate ambulance locations in different counties, you would have to keep three sets of records. When moving controlled substances from one location to another, required transfer records would have to be executed and maintained. Controlled substances may not be moved between locations or administerd from one DEA registration and restocked from another without the proper transfer forms

Any controlled substances that are kept apart from the vehicle needs to be stored at a registered location. A new application can be found by clicking **here**: The application form needed is a DEA-224 form, and then select "Ambulance Service" from the pull-down menu. The Medical Director's name goes on the first line, and the ambulance company's name goes on the second line. Only those services that are directly tied to a state entity are fee exempt.

What is required for accurate record keeping?

A registrant is required to maintain a file of receipt records that documents the receipt of all controlled substances received. The receipt records should be in a separate file from the DEA Form 222 Official Order Forms used for Schedule II drugs. Registrants must maintain the following information for all controlled substances received:

1. Date of receipt;
2. Drug name
3. Dosage form
4. Drug strength
5. Quantity received
6. Name, address and DEA number of the supplier
7. Name, address and DEA number of the recipient
8. Name or initials of employees verifying receipt of the drugs

These receipt records may be kept in a handwritten or typed log or may be maintained electronically. The third copies of all DEA Form 222 Order Forms must be signed and dated to verify receipt of the Schedule II drugs.

DEA Form 222 Order Forms should be kept for a period of 2 years. If they are not used, they should be voided and maintained on file. If a DEA Form 222 Order Form is ever lost, it should be immediately reported to the DEA.

If a registrant chooses to use a supplier's invoice, billing record, or packing document as a record of receipt, it that registrant's responsibility to review the document to make sure that the required information is documented on the receipt record.

How often should inventories be taken?

After an initial inventory has been completed the day the registrant first started stocking controlled substances, the registrant shall take a new inventory of all Schedule II drugs, Schedule III-V drugs and all dangerous/legend drugs on hand **at least once a year**. The annual inventory may be taken on any date that is within one year of the previous annual inventory date. **This means that a Service must keep three inventories; one for Schedule II drugs, one for Schedule III-V drugs and one for dangerous/legend drugs.**

The same information must be maintained in the annual inventory as for the first initial inventory. All the following information listed must be documented.

1. Date
2. Documentation of whether the inventory was taken at Opening of business or Closing of business or time of inventory if practice location is open 24 hours a day.
3. Drug name
4. Drug strength
5. Dosage form
6. Quantity of dosage units on hand

Schedule II drugs should be documented on a separate form. Do not combine non-controlled drugs on the annual controlled substance inventory.

How should you dispose of partially used controlled substances (a.k.a. waste)?

As defined in EMS Rules and Regulations Section XIV E. 8. Records of Controlled Substances:

When breakage or wastage of a controlled drug occurs, the amount administered and the amount wasted must be recorded by the Paramedic or other licensed healthcare provider who wasted the drug and verified by the signature of a licensed healthcare provider and/or licensed Paramedic who witnessed the wastage and how it was wasted.

Every milliliter and milligram of controlled substances must be accounted for. In the event that an entire syringe of a controlled substance is not administered, the unused portion that has been contaminated by patient contact may be wasted. The agency may document "wastages" on their administration log or they may have a separate document in the same file for the documentation of waste. When controlled substances are wasted because of contamination by patient contact, the following documentation must occur:

1. Log must have registrant's name and address
2. Date of wastage
3. Time of destruction/wastage
4. Patient's name
5. Drug name, drug strength, and quantity destroyed
6. The reason for the wastage
7. Signature or initials of the person performing the destruction
8. Signature or initials of the second person witnessing the destruction

When drugs are wasted or destroyed, they must be destroyed beyond reclamation.

What should be documented on the EMS encounter form or Patient Care Record?

All activities with controlled substances must be documented in patients' charts or your method of tracking administrations, i.e. trip tickets or medication administration records. Each administration must be documented in the patient's chart and include the given date, patient name, address, drug name, strength, dosage form, and quantity. Records must be maintained for a minimum of two years.

What does the term "positive identification" mean?

"Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug. Positive identification includes a manual signature on a hard copy record or report.

Note: Positive identification must be attached to a run sheet, or other drug record, only by the specific individual that personally administered the drug. Another person cannot attach positive identification to drug administrations that they did not personally administer.

Examples of common positive identification practices:

- Hand written run reports, with the wet-ink signature (i.e., not electronic) of the EMS personnel that administered a dangerous drug.

- Computerized run reports that are printed out, and signed in wet-ink by the EMS personnel who administered dangerous drug.

What should you do if drugs are discovered to be missing?

As defined in EMS Rules and Regulations Section XIV D. Procedures in Case of Loss of Controlled Substances.

1. Each Licensed Ambulance Service or Medical Director shall notify the Office of Pharmacy Services and Drug Control, Arkansas Department of Health immediately upon discovery of any suspected loss, theft and/or other diversion of any controlled substance under their supervision. Additionally, 21 CFR Part 1301.74 (c) requires notification of the Field Division Office of the Drug Enforcement Administration (DEA) in writing within one business day of discovery of the theft or loss.

2. The original and one copy of the DEA Form 106 shall be sent to the DEA Resident Office and one copy shall be sent to the Pharmacy Services and Drug Control and Section of EMS within seven days.

What should you do if drugs appear to be damaged or tampered with?

Any dangerous drug showing evidence of damage or tampering shall be removed from stock and replaced immediately secured at the office until an investigation can be conducted by the EMS Service supervisors or owner. If no foul-play is found, the medication must be taken to the Health Department to be destroyed and documented on the DEA-41 form. The drug, the DEA-41 and a health department form should be filled out, witnessed and then maintained with all the other records that are required to be kept. If foul-play is found, you should contact the police and the drugs turned over for evidence/analysis after contacting the required agencies.

Note: Tampering with dangerous drugs is a criminal act, and must be reported to the Section of EMS and local law enforcement.

When an EMS vehicle is removed from any licensed facility for service or maintenance should all the drug stock be removed?

Yes. All dangerous drugs shall be removed from the vehicle and properly secured at the licensed facility until such time as that vehicle returns to service.

What are the record retention requirements for drug accountability and security?

As defined in EMS Rules and Regulations Section XIV E. 8. Records of Controlled Substances:

1. The ambulance service Medical Director is responsible for maintaining accurate and complete records of such drugs received and a record of all such drugs administered, or professionally used otherwise.* Exception: Hospital based Service (The hospital's DEA Registration allows for the drugs to be supplied to the service through the hospital pharmacy where records of administration and distribution are the responsibility of the hospital).

2. The basic records are: receipt and disposition of controlled drugs within the service, patient medical records (Encounter Forms), and the controlled drug procurement and disposition records.

3. The record shall in every case show the date of receipt, the name and address of the person or business from whom received and the kind and quantity of drugs received.

4. The record shall show: the drugs administered, date of administration, the name and address of the person to whom or for whose use the drugs were administered, and the kind and quantity of drugs.

5. Patient medication records shall consist of at least, (a) physician's order authorizing the dispensing and administration of medications (Standing Orders), (b) medication administration record indicating the date, time and signature of the Paramedic or other licensed healthcare provider administering controlled drugs to the patient, and (c) the Paramedic or other licensed healthcare provider notes indicating the date, time, method of administration, and condition of the patient before and after the controlled drugs were administered and signature of the Paramedic or other licensed healthcare provider administering the drug.

6. In addition to patient's medical records, a record of the procurement and disposition of controlled drugs must be maintained.

7. The disposition record must reflect the actual dosage administered to the patient, the patients name, date, time and signature of the Paramedic administering the controlled drug. Any error of entry on the disposition and procurement record shall follow a policy of correction of errors and accurate accountability. If the person who procures the controlled drug is not the person who administers the drug, then both persons must sign the disposition record.

8. When breakage or wastage of a controlled drug occurs, the amount administered and the amount wasted must be recorded by the Paramedic or other licensed healthcare provider who wasted the drug and verified by the signature of a licensed healthcare provider and/or licensed Paramedic who witnessed the wastage and how it was wasted.

9. Adequate accountability does not require the use of a specific system or form. The system employed must be designed so that all requirements listed are met.

10. Each licensed ambulance service shall maintain inventory records in one consolidated record system. Records of Schedule II substances shall be maintained separately from all other records. Inventories of Schedule III, IV and V shall be maintained either separately from all other records or in such form that the information required is readily retrievable from the ordinary business records.

11. Every record shall be kept by the registrant and be readily retrievable and available for at least two (2) years from the date of the recording for inspection and copying by authorized agents of the Office of Pharmacy Services and Drug Control, Arkansas Department of Health, or the Section of EMS.

Who is ultimately responsible for the drug accountability and security for an EMS Service?

The registration belongs to the medical director, not the ambulance company and as such, he is the person responsible for the registration, drugs and all the corresponding record keeping and security requirements. Therefore all sanctions including any fines levied by the DEA will be against the medical director of the EMS Service. For more detailed information to share with your medical director, please follow this link: **Office of Diversion Control, Practitioner's Manual**.

Do all EMS Service Medical Directors have to be Arkansas Licensed?

Yes. Each medical director who is overseeing an ambulance service in Arkansas must have a valid Arkansas medical license **AND** a DEA registration at the facility's site in which controlled substances are stored.

If we have multiple DEA registrations can we order only off of one to supply all permitted ambulances or to replace controlled substance storage.

No. The registered location is the only location where controlled substances can be ordered, received and distributed. Once the drugs are placed on the ambulance, they cannot be taken off unless it's to be placed back in a secure location at the registered location or they were administered to a patient.

What are the security requirements for the storage of IV solutions?

As defined in EMS Rules and Regulations Section XIV H. Storage of Pharmaceuticals by licensed Ambulance Services

1. All pharmaceuticals will be stored in accordance with the instructions included in the package inserts of each drug. Factors such as heat, freezing, susceptibility to light, etc., are described in the insert, and all services will provide suitable storage to comply with the instructions.

2. Freezing is defined as storage at temperatures at or below 32 degrees Fahrenheit Excessive heat is defined as temperatures at or above 104 degrees Fahrenheit (104F). The licensee will provide protection of fluids and pharmaceuticals on units.

What type of licenses does an EMS organization need to possess dangerous drugs?

Arkansas EMS Service License:

All EMS Service must have a valid Arkansas EMS Service License

DEA Registration:
A separate registration in the name of the Medical Director (Physician) is required for each service license place of business at one general physical location where controlled substances are maintained or distributed to ambulances specifically licensed to maintain drugs.

Who will the Section contact should violations arise during an inspection?

The Section will contact the US Drug Enforcement Administration, The Department of Health Pharmacy Services and Drug Control Section and the Service Medical Director. Should diversion issues be documented, local law enforcement will be notified as well.

What are some Best Practices for Security of Controlled Substances?

1. Routinely review controlled substance laws and regulations so you are familiar with what is required.
2. Contact authorities when you have questions or concerns.
3. Implement a written policy and procedure of how and by whom controlled substances are to be handled in your agency and what is required.
4. Conduct periodic training meetings to ensure that your staff knows what is required and how to comply with laws and policies.
5. Conduct periodic reviews and self-inspections of your own practice to ensure that you and your employees are consistently complying with policies and laws.
6. Periodically audit and reconcile your drug counts against the record keeping to ensure that all drugs are accounted for, drugs are not missing, and there are no record keeping errors.
7. Most ambulance services have the drugs on the ambulances counted with each shift change, by one employee going off duty and one employee who is coming on duty.
8. When possible, have all controlled drug activities performed by two people.
9. It is very important that when counting and inventory, employees should be trained to check for tampering, torn packaging, or holes in packaging. The most common method of theft in an ambulance service is to steal the drugs and replace the drugs with water so the containers appear full.
10. The person who orders and purchases the drugs should be a different person than the person who receives, checks them in and adds them to inventory. These should ideally not be the same people who also pay the bills. Separate the duties of ordering, receiving and paying so there are checks and balances.
11. Review your invoices from drug companies to make sure you authorized the drugs purchased.
12. The person who receives controlled substance shipments and checks them in should have a second person verify what was received and that the drugs are accurately being added to the perpetual inventory logs.
13. Although not required, perpetual inventory logs are encouraged to provide an ongoing record of what you have administered and what you have remaining.
14. Do not allow patients and visitors access to drug supplies. This means if drugs are missing, it is an employee who is responsible. Although we trust our employees, it is often the staff in a practice that divert drugs because they are ones who have access and can falsify records. Policies are put in place to protect your registration and provide clear notice of expectations and oversight.
15. Employees should be comfortable with policies and procedures that require oversight and witnesses because if there is a discrepancy in the drug count, consistent compliance with policies can protect them from false accusations.
16. Restrict the number of people who have access to your drugs to the fewest people possible.
17. Have a policy requiring random drug testing. Even if you do not want to conduct random drug testing on a regular basis, you should be able to demand a drug test during the course of an internal investigation should drugs be missing.
18. Periodically review your administration and dispensing logs to make sure that an employee has not removed drugs and made up a name of a fictitious patient you don't remember treating.
19. Set up a calendar or reminder system so you know when it is time for an annual inventory or renewal of licenses and registrations.

How to perform an audit of your controlled substances.

While the following information is routine for many from time to time we receive questions on how to perform an audit of your controlled substances. The following is an example of how it should be completed.

Start with the drugs you had on hand from your last annual inventory	200 ml	morphine
Add the drugs you purchased or received from other registrants (This includes all receipts and samples received)	2,500ml	morphine
Total quantity you are responsible for	2,700ml	morphine
Calculate the amounts of drugs you have administered & wasted	1,200ml	morphine
Losses and thefts report to the Department of Health and DEA	5ml	morphine
Total number of drugs you no longer have	1,230ml	morphine

Drugs you're re responsible for 2,700ml minus the number of drugs you no longer have (1,230ml) leaves you with the 1,470ml that should be in your possession.

If you have 1,470ml on hand, then your drugs are accounted for.

If you have a discrepancy, then you either have a record keeping problem or you are missing drugs.

Diversion of controlled substances by employees

Although it is unfortunate, many of us have heard stories of ambulance services having their controlled substances stolen by employees. In almost all instances, when controlled substances are stolen from an ambulance service, they were stolen by an employee who was in a trusted position. Ambulance services do not normally allow visitors and unauthorized persons access to controlled drugs. When drugs are discovered missing, it is normally a trusted employee who committed the diversion. It could be for their personal use or they could be selling it or providing drugs to a friend or relative. These record keeping systems and security measures are set in place for a multitude of reasons:

- To prevent the diversion of controlled substances;
- To detect the diversion of stolen controlled substances;
- To protect the employer's registration;
- To protect the honest employees with a system of checks, balances and witnessed activities;
- To protect the public's health and safety. The practitioners treating the public should not be impaired on illegally administered drugs and the medications the public receives should not be diluted.
- In very simple terms, these records and security measures should be maintained because it's the law.