

**STATE OF ARIZONA • EMERGENCY MEDICAL SERVICES AND TRAUMA SYSTEM**

**Controlled Substance Storage Security Guidance**

**Background**

The Bureau of Emergency Medical Services and Trauma System (Bureau) has developed the following guidance document as technical assistance to the EMS community to identify and discuss areas of vulnerability in the storage and maintenance of EMS medications.

**Statutory & Regulatory Authority**

Arizona Revised Statutes (A.R.S.) § 36-2202 (A)(4): The director shall: adopt rules necessary to carry out this chapter.

Arizona Administrative Code (A.A.C.) R9-25-201(F) establishes prescriptive criteria for agents and controlled substances.

**Definitions**

- “Agent” means a chemical or biological substance that is administered to a patient to treat or prevent a medical condition.
- “Controlled substance” has the same meaning as in A.R.S. § 32-1901, to be inclusive of but not limited to opioids and benzodiazepines.
- “Authorized EMCT,” for the purpose of this guidance document, means an Emergency Medical Care Technician (EMCT) having medical direction and acting under an ALS scope of practice, as identified in 9 A.A.C. 25, Article 5.

**Process**

The following document was developed to provide guidance for EMS agencies, to promote best practices on compliance with applicable rules and statutes regarding use, storage, administration, and wastage of pre-hospital agents and controlled substances utilized by authorized EMCTs and Emergency Medical Services provider organizations. It is important to continually evaluate the need for improving security and control measures in an operational area that, if mismanaged, could impact patient safety and provider safety, and affect public trust.

**Drug Box Containers:** The Arizona Administrative Code is silent on the brand, material, or style of drug box the EMS community is required to utilize in the field. It does prescribe that:

1. An agent must be secured in a dry, clean, and washable receptacle;
2. While on a motor vehicle or aircraft, an agent must be secured in a manner that restricts movement of the agent and the receptacle; and
3. Controlled substances, when not in use, must be stored in a locked container that is difficult to breach without the use of a power cutting tool.

**Drug Box Cleanliness:** When a drug box is used, an EMCT is responsible for keeping the container clean and free of blood or other body fluids and protected from other damaging conditions.

**Written Chain of Custody:** A.A.C. R9-25-201 describes documentation criteria for each EMCT who takes custody of a supply of agents. Each time an EMCT takes custody of a supply of agents/controlled substances, that EMCT must perform an inventory of the agents/controlled substances. The following information must be documented on a written chain of custody log for each individual who takes custody of the supply of agents:

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1. The name of the authorized individual,
2. The EMCT certification number or employee identification number,
3. The Date and Time the drug box was initially received, and either
4. The Date and Time the drug box was placed in secure storage at an employer-defined authorized facility,  
or
5. The Date and Time the drug box was transferred to another authorized individual.

**Inspection of Agents/Controlled Substances:** All EMCTs should inspect the drug box and inventory the agents/controlled substances prior to accepting custody at the beginning of the shift. The drug box must contain at least the minimum supply of agents required for the highest level of service to be provided by the EMCT.

Whenever there is a transfer of the drug box to another authorized EMCT, both EMCTs should inspect the drug box and inventory the agents/controlled substances prior to transferring custody.

Inspection of any supply of agents/controlled substances needs to address all of the following:

1. Expiration dates
2. Deteriorated or contaminated agents
3. Container/label damage
4. Altered labels
5. Tampered seals
6. Depleted supply levels
7. Missing agents

If any of the conditions are noted:

1. Document any of the conditions;
2. Obtain a replacement for each affected agent for which the minimum supply is not present; and
3. Notify the administrative medical director of a depleted, visibly adulterated, or missing controlled substance.

**Inspection of Individual Agent Containers and Seals:** Controlled substance individual containers are to be sealed at all times when not in use. Should a seal be found broken or opened, but not used, the contents need to be inspected immediately by an authorized individual and returned to the base hospital pharmacy or Emergency Medical Services provider to be exchanged. During any inspection of the agents/controlled substances, authorized EMCTs should consider it best practice to observe the following:

1. Container end caps for needle puncture holes
2. Container caps for glue around the base of the rubber stopper
3. Container caps
4. The color of the contents
5. The presence of debris inside the container
6. Labeling abnormalities
7. Appropriate amount of controlled substance in the container
8. Syringe activation systems that have not been activated

**Storage and Security:** Each individual drug box should be locked or sealed. Should the security device or seal be found broken, or a drug box opened, the contents need to be inspected and inventoried immediately by an authorized EMCT.

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If the security device or seal on the drug box is discovered missing while performing patient care or after arriving at the hospital:

1. Continue patient care; you may continue to utilize the contents of the box.
2. If the medication needed is not present, consider requesting another unit to meet on scene, but do not delay response or transport.
3. Conduct an inspection and inventory.
4. Notify the EMS employer/supervisor.
5. Notify the administrative medical director and/or base hospital pharmacy of a depleted, visibly adulterated, or missing controlled substance.

**Administration of Agents/Controlled Substances:** A.A.C. R9-25-502 Tables 5.1 and 5.2 provide a list of scope of practice and agents/controlled substances authorized for administration by EMCTs in Arizona.

Each authorized EMCT shall document the following information on the patient care report:

1. Date and time of administration
2. Patient name
3. Patient address or scene location/identifier
4. Drug name
5. Dose of each administration
6. Route of administration
7. Effects of medication

Records should account for the use and disposition of all controlled substances utilized by an authorized EMCT.

**Documenting Wastage of Controlled Substances:** Authorized EMCTs must account for any useable quantity of a controlled substance. Unused quantities of controlled substances should be wasted beyond reclamation and witnessed by a minimum of one additional authorized person and the following documented on the patient care report and/or chain of custody log based on medical direction or Emergency Medical Services provider policy:

1. Date of wastage
2. Time of disposal/wastage
3. Patient's name
4. Drug name, drug strength, and quantity destroyed
5. The reason for the wastage
6. Printed name and Signature or initials of the person performing the disposal
7. Printed name and Signature or initials of the second person witnessing the disposal

**Transfer of Agents Between Agencies:** The transfer of controlled substances between agencies/providers in the field should be highly controlled through EMS administrative medical direction policy. This practice should only occur in settings where extended out-of-service hours are required to replace patient use medications. According to A.A.C. R9-25-201 (E)(3)(b)(iv), the transfer of controlled substances between agencies may only occur within the same administrative medical direction system if:

1. The Medical Director has identified and authorized individuals who have access to the agents.
2. The agencies maintain a chain of custody for the agents. (Chain of custody can be met through the use of a transfer-of-agents document approved by the administrative medical director.)
3. The transfer-of-agents document should be forwarded to the pharmacy replacing the agent for the resupplying agency, to adhere to the chain of custody requirement.

**Disposal of Controlled Substances:** Outdated, expired, deteriorated, damaged, or altered containers or labels of agents/controlled substances may only be destroyed by a base hospital pharmacy or, if the controlled substances are owned by an Emergency Medical Services provider organization, after prior approval from the United States Drug Enforcement Administration (DEA).

Return agents/controlled substances that are outdated, expired, deteriorated, damaged, or have altered containers or labels to the base hospital pharmacy or the Emergency Medical Services provider, whichever owns the agents, for the legal disposition of unwanted controlled substances in accordance with [DEA regulations](#).

**Breakage and Spillage of Controlled Substances:** Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements.

If the breakage or spillage is not recoverable, document the circumstances of the breakage in the inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. Notify the Emergency Medical Services provider manager. Obtain a replacement quantity. The submission of a DEA Form 41, *Registrants Inventory of Drugs Surrendered*, is not required for non-recoverable controlled substances.

If the base hospital pharmacy retains ownership of the controlled substances, the base hospital pharmacist-in-charge will be immediately notified.

**Reporting Losses and Thefts:** Each time agents/controlled substances change hands or are used, documentation must be generated and maintained. There should be a paper trail to show the path of a controlled substance dosage unit from the day it was manufactured, through the distributor, to the hospital, pharmacy, Emergency Medical Services provider organization, authorized EMCTs, then the patient.

It is extremely important for authorized EMCTs to know and comply with controlled substance policy, base hospital and regional protocols, and regulatory laws. If an EMCT commits an infraction, the employer's DEA registration or Certificate of Necessity may be at risk, as well as any personal certification held. Emergency Medical Services provider organizations usually base their policies on state and federal laws; violating a written policy may, in many cases, be violating the law.

Whenever a controlled substance is missing and cannot be accounted for, then it is a reportable loss. All reportable losses, thefts, and diversions of controlled substances must be reported to the administrative medical director, following the service provider's chain of command, and, if a base hospital retains ownership of the agents, the base hospital pharmacist-in-charge immediately. The Administrative Medical Director must notify the Bureau within 10 days after discovery.

A base hospital pharmacist or the Emergency Medical Services provider (if the controlled substances are owned by the provider) should conduct an internal review and investigation to determine the manner of theft or loss and determine the amount missing. In cases of loss, theft, or diversion of controlled substances, local law enforcement should be contacted to conduct an independent investigation.

A base hospital pharmacist or the Emergency Medical Services provider (if the controlled substances are owned by the provider) must report to the DEA within 1 day.

The DEA form may be submitted electronically on their website at [www.deadiversion.usodj.gov](http://www.deadiversion.usodj.gov).

It is best practice for Emergency Medical Services provider organizations and base hospital medical directors to both periodically review and conduct random inspections of agents, controlled substances inventory, and chain of custody documents.

Individual EMCTs who demonstrate a noted increase or change in the pattern of administration of controlled substances should also trigger concern with their Emergency Medical Services provider organizations and Administrative Medical Directors. EMS personnel who divert drugs for personal use place their patients, their employers, and their coworkers at risk.

Emergency Medical Services provider organizations are required to have adequate controls in place to detect and address the diversion of controlled substances as prescribed by the DEA. Security measures include policies, best practices, and required record keeping such as:

1. All controlled substances in a building or on a transport vehicle must be stored in a securely locked substantially built safe or cabinet.
2. The security provided must be commensurate with the quantity and types of controlled substances on the transport vehicle.
3. Controlled substances may not be left unattended where unauthorized persons would have access to them.
4. Controlled substances on ambulances must be stored in locked containers and storage areas.
5. Access to controlled substances should be restricted to the fewest people possible.

EMCTs are prohibited from allowing patients and visitors access to drug supplies.

EMCTs arriving at a receiving facility should be constantly vigilant in maintaining a level of security for the drug box and its contents, which typically remain on the transport vehicle while the patient is moved inside the facility.

An Emergency Medical Services provider organization, base hospital or administrative medical director should have policies in place allowing the request of a drug test during the course of an internal investigation of a drug loss, theft, or suspected diversion of controlled substances. It is best practice for Emergency Medical Services provider organizations, base hospitals, or administrative medical directors to request a timely drug test during the early course of an internal investigation. A third party lab should be used for definitive results based on the drug identified during the initial loss report.

**Training:** Utilizing case studies from investigation files to update current written procedures provides EMCTs with information on the current trends in diversion and assists with recognition of a co-worker who may be under the influence of controlled substances.

Training and quality improvement programs that include instruction on checks and balances related to controlled medication inventories would discourage tampering with or stealing controlled medications. With the introduction of this guidance document, Emergency Medical Services provider organizations and base hospitals have an opportunity to analyze, modify (where necessary), and conduct current and topical training for EMS personnel. Developing standard tools such as log forms and policies would serve to maintain consistency across EMS agencies/regions.