University of Arizona, Division of EMS

EMS Medication Policy Overview

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- Definition of Terms
- General requirements for Obtaining, Storing, & Transferring of Medications
- Medications from a Certified ALS Base Hospital
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- Controlled Medications
- Regulated Medications

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- Controlled Medications
- Regulated Medications

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EMS Medication Policy

Purpose:

- To provide a process for EMS agencies to obtain, store, and manage controlled substances and regulated medications for use by certified EMCTs.

Definitions:

- Independent EMS Medications: Medications purchased directly by an EMS agency from a licensed pharmaceutical supplier under a current written agreement, stored at a secure EMS station, and used for routine EMS patient care. These medications are obtained and maintained independently from any certified ALS base hospital.
- Controlled Substance: Medications regulated under the DEA) schedules and authorized for EMS use in accordance with applicable federal and state laws. Controlled Substances include, but are not limited to:
    - Narcotics: Morphine
    - Benzodiazepines: Midazolam (Versed), Lorazepam (Ativan)
    - Other: Ketamine
- Regulated Medications: Medications approved for EMS use that are not listed as Controlled Substances under DEA schedules but remain subject to agency, state, and medical direction oversight.
- Drug Box: A secure container(s) used to store and transport medications within EMS response apparatus.
- Medication Storage Unit: A commercial, locked storage unit located in a secure location.
- Independent EMS Medication Program: A program operated by an EMS agency and approved by the Administrative Medical Director authorizing the agency to purchase, store, manage, and replenish EMS Drugs Boxes, and to administer medications during routine EMS operations, independent of a Base Hospital.
- Authorized EMCT or RN: A certified Emergency Medical Care Technician or registered nurse who is authorized under this policy to handle, administer, and account for Controlled Substances, and who meets the qualifications outlined in Section III(D)(2) of this policy.

Policy:

- Common Requirements for ALL EMS medications:
    - The EMS agency Administrative Medical Director or their designee must approve:

        - All BLS medications utilized by BLS providers and any par level above DHS minimums.
        - All ALS medications utilized by ALS Providers and any par level above DHS minimums.
    - All medications accessible to an EMCT must be within the EMCTs scope of practice.

- Independent EMS Medication Program Oversight Officer:
    - The EMS agency will designate a single individual the "Independent EMS Medication Program Oversight Officer," to oversee the EMS medication program who will:
        - Be certified EMCT
        - Ensure that all EMS Medical Policies are followed.
        - Meet with the Administrative Medical Director or their designee at least annually to review the controlled substance program, policies, procedures, records, and audit which will include:
            - Review all EMS medication records annually to ensure compliance.
            - Conducting an annual on-hand inventory of all current medications.
        - Be present for any DEA or other regulatory inspections.
        - If the EMS agency has independent on-site controlled substances, the program oversight officer will coordinate the receipt of controlled substance as outlined in III(F)(3).

- Medications obtained from a certified ALS Base Hospital:
    - The EMS agency shall follow the policies and procedures of the ALS Base Hospital for obtaining, storing, transferring, and disposal of any medication.
    - The EMS agency shall immediately report any Controlled Substance discrepancy to the ALS Base Hospital and the Administrative Medical Director.

- Regulated Medication(s) obtained through an Independent EMS Medication Program require:
    - A secure climate-controlled area designated for the storage of Regulated Mediations.
    - An established agency process for tracking each medication from purchase and delivery through placement in the EMS drug box, and for reordering following patient use or expiration.
- Controlled Substances: obtained through an Independent EMS Medication Program require:
    - Once the controlled substance is placed into the medication storage unit, items III(F)(2,4,5) of this policy will apply and all associated EMS medication policies will apply with the exception of the EMS Medication Record Keeping Policy item III(3)(B)(1)(a&c) and item III(B)(2)(b) .

- Once the controlled substance is placed into the medication storage unit all policies relating to the storage, utilization, and wasting of controlled substances will apply.

- Controlled Substance(s) obtained through an Independent EMS Medication Program require:
  - DEA Registration
    - The Administrative Medical Director or Associate Medical Director (DEA Registrant) must obtain a DEA registration for each site at which a Controlled Substance will be stored.
  - Agency Employee Screening:
    - The EMS agency will ensure that an employee(s) who has access to Controlled Substances attests to and has a background check to confirm that they have not:
      - Been convicted of a felony within the last 5 years
      - Been convicted of a misdemeanor within the last 2 years
      - Used non-prescribed substances within the last 3 years
    - Documentation of employee screening / attestation must be kept on file for review.
  - Ordering, Receipt, and Replenishment of Controlled Substances at a registered site.
    - Ordering Controlled Substances:
      - Must be approved by the DEA Registrant and completed using Form DEA-222 obtained from the Controlled Substance distributor.
    - Receipt of Controlled Substances:
      - The DEA Registrant or their designated representative must take receipt of all controlled substance(s) from the distributor at the site address registered with the DEA and place the controlled substance in the Medication Storage Unit.
      - The DEA Registrant may designate a representative(s) via power of attorney (POA) to receive the controlled substance(s).
      - POA documentation must be kept on file with all Form DEA-222s used to order controlled substances
      - POA may be revoked at any time by the DEA registrant.
    - Replacement of used / expired Controlled Substances(s) will only be done:
      - By the EMS provider who administered or identified the expired Controlled Substance(s).
      - By an EMS captain who is transporting a single dose of medication to maintain agreed upon EMS Drug Box medication par level.
      - The Medication Storage Unit will not be used to distribute controlled substances.

- Field exchanges will **not** be permitted unless both agencies are working under the same Administrative Medical Direction, and both agencies have a written agreement to allow drug exchange, which has been approved by the Medical Director who holds the DEA license.

- Storage and Security of Controlled substance:
  - For all Controlled Substances the EMS agency will:
    - Only store Controlled Substances(s) at a location(s) for which the DEA Registrant is registered with the DEA and for which a valid Controlled Substance Registration Certificate is on file.
    - Controlled substance must be stored in an approved commercially available Medication Storage Device.
    - Access to and security for all Controlled Substances must meet the requirements outlined in DEA Title 21, code of regulations section 1301
    - The EMS agency will submit a proposed security plan for the storage of Controlled Substances to the DEA Special Agent in Charge for review prior to stocking Controlled Substances.
- Controlled substance records:
  - The EMS agency will keep all recording pertaining to obtaining, storing, transferring and disposal of Controlled Substances for a period of 3 year as outlined in the EMS Medication - Record Keeping Policy

Associated Policies:

- EMS Medication - Drug Box Security and Usage Policy
- EMS Medication - Record Keeping Policy
- EMS Medication - Wastage Policy
- EMS Medication - Discrepancies Policy

Appendix

- Medical Director Designation of POA
- Medical Director Revocation of POA

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EMS Medication Policy

Appendix 1: Medical Director Controlled Substance Power of Attorney

Power of Attorney for DEA Forms 222 and Electronic Orders

_____ (Name of registrant)

_____ (Address of registrant)

_____ (DEA Registration Number)

I, _____, the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint (name of attorney in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

_____ (Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____ (signature of attorney-in-fact)

Witnesses:
1. _____

2._____

Signed and dated on the ____day of _____, 20__, at _____ .

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Appendix 1: Medical Director Controlled Substance Power of Attorney

Notice of Revocation

Power of Attorney for DEA Forms 222 and Electronic Orders

_____ (Name of registrant)

_____ (Address of registrant)

_____ (DEA Registration Number)

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____ (signature of person revoking power)

Witnesses:

1. _____

2._____

Signed and dated on the ____day of _____, 20__, at _____ .

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EMS Medication - Drug Box Security Policy

Purpose/Expected Outcome:

- To ensure compliance with the requirements established by the Department of Health Services and Drug Enforcement Administration (DEA) regarding the security, storage, and use of pre-hospital drug boxes.

Definitions:

- Refer to EMS Medications Policy

Policy:

- Only authorized EMCTs, or registered nurses may administer medications under the medical direction of a medical direction authority in accordance with R9-25-202.
    - When a controlled substance is ordered, an EMCT, or registered nurse shall:
        - Document the Administrative or Standing Order or the online medical direction order on the pre-hospital incident form.
        - If the order was given online, a signed form is needed by the medical direction authority providing the order.
- Drug Box Security
    - The EMS agency is responsible for maintaining drug box security.
    - The drug box shall be stored:
        - In a locked compartment that prevents unauthorized access
        - In a manner that restricts movement while the vehicle is in motion.
    - Unauthorized individuals shall not have access to the drug box.
    - Medications shall be maintained at manufacturer-recommended temperatures.
    - When a drug box is assigned to an EMCT or RN, the following must be recorded in writing:
        - Name of the individual
        - Time and date of assignment.
        - The agency shall retain these records for at least three (3) years from the date of entry.
- Drug Box Construction and Identification
    - The agency shall provide a drug box that is:
        - Clearly identified as an BLS or ALS Drug Box
        - Washable, lockable, and is large enough to contain all of the drugs listed in R9-25-502.
        - Includes a contents list showing the location and identification of drugs.
- Drug Box Verification and Inspection
    - The assigned EMCT or RN shall check the drug box at each shift change or transfer of responsibility for:

        - Expired or deteriorated medications,
        - Damaged or altered containers or labels,
        - Missing medications.
    - If any discrepancies are found notify agency leadership in accordance with the EMS Medication Discrepancy Policy.
    - The outgoing provider shall verify the inventory before transfer to the next assigned EMCT or RN.
        - This verification must be in writing and include the name or certification number, date, and time of inspection.
    - All medication administrations shall be documented on the pre-hospital incident form in compliance with R9-25-201(E)(3).
- Controlled Substance Discrepancies
    - Should an EMCT, or a registered nurse find any of the conditions found in Policy statement (D)(1) above for a **controlled substance,** the Administrative Medical Director, within 10 days of notification, shall notify the Arizona Department of Health Services/Bureau of Emergency Medical Services, in writing specifying the date of the discovery, type of controlled substance involved and the type of exception.
- Drug Re-Supply
    - The agency shall exchange or re-supply drugs only from a receiving health care institution, through an EMS Medication Program or with a certified ALS base hospital with which the agency has a written agreement for re-supplying drugs.
    - The agency will re-supply on a drug-to-drug basis.
    - The agency shall assure that the EMCT, or registered nurse will document the exchange on a form that includes the name of the drug exchanged and the date and time of exchange.
- Drug Box Contents and Accountability
    - Except as provided in subsection (G), the contracted pharmaceutical supply company or ALS base hospital's pharmacy shall provide the contents of a drug box in the supply ranges set forth in Table 1, R9-25-502 or in excess of these levels only with the approval of the Administrative Medical Director or Associate Medical Director.
    - The number of ALS / BLS drug boxes maintained by an EMS agency must be approved by the Administrative Medical Director.
    - The contents of each ALS or and the location and responsible EMCT for each drug box will be agreed upon by the agency and Administrative Medical Director
    - The EMS agency is responsible for keeping a current and accurate log of the location and responsible provider for each ALS/BLS drug box for the past 3 years.
- Inter-Facility Transport of IV Medications
    - A certified medical technician shall receive approval of the Administrative Medical Director before inter-facility transport of an individual receiving any drug listed in Table 5.4 of R9-25-502.

    - An EMCT shall receive training in the administration of a Table 5.4 drug before monitoring an IV infusion delivery during an inter-facility transport of an individual.
    - Before an infusion pump is used for drug delivery, and EMCT shall receive training in the administration of a Table 5.4 drug and the use of the infusion pump that will be used to administer the Table 5.4 drug.
- Authorized Medications
    - Items in the drug box are restricted to those approved for use by the Administrative Medical Director and identified in Arizona Administrative Code R9-25-502, Table 5.2, under an emergency rule by the Arizona Department of Health Services Bureau of Emergency Medical Services ("ADHS/BEMS"). Exceptions can be made by the Medical Director for pilot studies, expanded scope of practice, such as; HazMat paramedics, Tactical Operating Unit paramedics, Wilderness paramedics, Wildland paramedics, or EMTs of all levels in a disaster situation

Other Related Policies/Procedures:

- R9-25-502
- R9-25-201, 202

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EMS Medication - Wastage Policy

Purpose/Expected Outcome:

- To ensure proper documentation, accountability, and disposal of all medications – particularly controlled substance – unused portion of medications or expired medications removed from service by EMS personnel.

Definitions:

- See EMS Medications Policy

Policy:

- For Regulated Medications:
    - Unused medication or expired medication should be deposed of in a manner that renders the medication unusable.
    - The empty medication vial may be thrown in the trash.
- For Controlled Substances:
    - Controlled substance wastage must be disposed of in accordance to State and Federal regulations.
        - All controlled substance wasted medication must be rendered "beyond reclamation"
        - For the disposal of medications left after patient use.
            - Wasting of excess controlled substances must be witnessed by an:
                - Approved EMCT / RN
                - Hospital RN or pharmacist
        - Expired controlled substances:
            - Must be held in a secure location and separate from the usable stock of medications until appropriate disposal can be secured.
            - Must be disposed of using a Medical Director approved "Reverse Distributor" and an appropriate DEA form 222 completed for all expired controlled substances.
                - All records for the disposal of controlled substances must be maintained as outlined in the EMS Medications – Record Keeping Policy"
        - If an EMS agency desires to dispose of medications on site the EMS agency must obtain approval from the DEA special agent for on-site disposal of expired controlled substances and use an approved method of destruction.
    - For controlled substances that are replaced at a receiving facility.
        - Excess controlled substance will not be wasted on-scene.
        - The vial/ampule identifying the controlled substance and the unused portion of the controlled substance will be brought to the Emergency

Department (ED) and wasted in the presence of the Approved EMCT, RN, or Pharmacist
        - EMS providers should follow receiving facility policies for controlled substance replacement.
        - No portion of the unused EMS controlled substance will be administered by the receiving facility to the patient.
    - For controlled substances, that are replaced at the EMS agency Medication Storage Unit.
        - Excess controlled substance will not be wasted on-scene.
        - The vial/ampule identifying the controlled substance and the unused portion of the controlled substance will be brought to the Medication Storage Unit and wasted in the presence of the appropriately licensed personnel.
        - Medication to be wasted should be placed into a sand filled container
        - The medication vial must be placed in the Medication Storage Unit disposal slot
        - The Approved EMCT / RN will document and a second Approved EMCT / RN will witness the amount administered and destroyed:
            - On the EMS Encounter form of the patient receiving the controlled substance.
            - On the EMS Drug Box log
            - On the Medication Storage Unit log
    - For disposal of controlled substances which have expired but have not been used in patient care.
        - Expired controlled substance(s) must be wasted at the Medication Storage Unit location.
        - Two Approved EMCT(s) / RN(s) must inspect each vial for evidence of tampering.
        - If no evidence of tampering is found the complete contents of the vial can be drawn up and wasted as outlined in III.B.3 above.
        - The amount destroyed must be documented on form DEA-41.
        - Form DEA-41 must be kept by the EMS agency for a period of a least 2 years.

Additional Information

- Witness signatures for controlled substances are not meant to replace the signatures on the pre-hospital incident form required to “accept” or to “transfer” the patient.

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EMS Medication - Wastage Policy

Appendix 1

To Whom It May Concern,

We would like to request permission to perform on site disposal of controlled substances used in the day to day EMS operations performed by _____. _____will be stocking controlled substances under the license of DEA registrant _____. at the locations listed below. With your permission, we would like to dispose of excess medication or expired medication at the addresses listed below by placing the medication in a sand filled container which will render that medication beyond reclamation.

Registered locations include:

_____

_____

_____

_____

_____

Thank you for your assistance and please feel free to contact us with any questions or concerns.

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EMS Medication - Records Keeping Policy

Purpose/Expected Outcome:

- To establish standardized procedures for the documentation of and maintenance of records pertaining to the receipt, use, and/or disposal of Controlled Substances & Regulated Medications.

Definitions:

- See EMS Medications Policy

Policy:

- Minimum required documentation for EMS agencies with on-site controlled substances NOT contained in an ALS Base Hospital EMS Drug Box:
    - Documentation of purchase, receipt, storage, placement in the EMS Drug box, and patient use or expiration of medication must be maintained for all Regulated Medication for a minimum of 3 years.
- Minimum required documentation for EMS agencies with on-site Controlled Substances NOT contained in an ALS Base Hospital EMS Drug Box:
    - General Requirements:
        - Records must include the location of and person responsible for each vial of a controlled substance from the time it is received by the DEA Registrants authorized representative to time of administration or wastage.
        - All records must be kept by the EMS agency for a period of at least 3 years.
        - All records must be kept at the Controlled Substance storage site unless the agency has prior DEA authorization to store the records in a secure central storage location
    - Document receipt of the Controlled Substance and placement in the Medication Storage Unit
        - Date, Time, Medication Identification Number
        - DEA Registrant Authorized Representative and approved EMCT: name, certification number and signature of both individuals
    - Document Placement of the Controlled Substance into EMS Drug Box
        - Date, Time, Medication Identification Number
        - Two appropriately licensed individuals: name, certification number and signature
    - Document Controlled Substance use, wasting, and/or disposal.
        - When a controlled substance is administered during patient care and a residual amount must be wasted; the following shall be accurately documented and retained: the incident or run number, the dose

administered, the quantity wasted, and the signatures of two qualified (EMT, Paramedic, or RN) who directly witnessed and verified the wastage.
        - For expired controlled substances being disposed of using a revers distributor a DEA form 222 must be completed and kept on record for each dose of medication destroyed by used of a reverse distributor.
    - On-Hand Inventory:
        - At minimum, every 1 year the EMS agency in conjunction with the Administrative Medical Director or their designee will perform and document an on-hand inventory to identify any lost or missing controlled substance.
        - Any discrepancies will be reported as per the EMS Medications - Discrepancies Policy.

Additional Information

- Witness signatures for controlled substances are not meant to replace the signatures on the pre-hospital incident form required to “accept” or to “transfer” the patient.

Sample Letter Requesting Permission to keep Controlled Substance Records in a Central Location

To be sent to the DEA Special Agent

To Whom It May Concern,

We would like to request your permission to keep all records related to the Ordering/Purchase, Storage, and Use of the Controlled substances at a central location. We will be utilizing controlled substances at the locations listed below and would like to keep all records at the secure central location list.

Locations at which controlled substances will be utilized:
1.
2.
3.
4.

Record Keep Location:
_____

Thank you for your assistance and please do not hesitate to contact us with any questions or concerns.

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EMS Medication - Discrepancies Policy

Purpose/Expected Outcome:

- To provide a mechanism for the accurate accounting, reporting, and documentation of any medication discrepancies – including missing, stolen, tampered with, or depleted controlled substances.

Definitions:

- See EMS Medications Policy

Policy:

- Incidents that require reporting:
  - Any discrepancy in the stock of medications (depleted, stolen, or missing medication)
  - Any medication which appears to have been tampered with such as; broken seal, altered labels, or other container damage.
- Discrepancy Identification and Reporting
  - Upon discovery of any discrepancy, the EMS provider must:
    - Secure the medication storage area or medication box
    - Notify the supervisor and AMD immediately
    - Fill out a Medication Discrepancy Report?
- Incidents Involving Regulated Medications:
  - The EMS Officer will:
    - Review the last 3 months of Medication Storage Unit logs and Drug Box logs for the site at which the discrepancy was discovered.
    - Review both logs to identify any potential source of the discrepancy or tampering.
    - Implement a corrective action plan to reduce the risk of future incidents
  - The Administrative Medical Director or their designee will:
    - Review the incident and determine if reporting to the DHS is required.
    - Ensure that any appropriate corrective actions are implemented
- Incident Involving Controlled Substance(s):
  - The Controlled Substance Program Oversight Officer will:
    - File a police report and obtain a case number
    - Obtain the last 6 months of Medication Storage unit logs and Drug Box logs for the site at which the discrepancy was discovered.
    - Review both logs to identify any potential source of the discrepancy or tampering.
    - Arrange a meeting with the DEA Registrant to review the incident
    - Complete and submit DEA Form 106 and determine if the DEA requires any further action.
    - Implement a corrective action plan to reduce the risk of future incidents

- The Administrative Medical Director or their designee will:
    - Review the incident and determine if reporting to the DHS is required.
    - Ensure that any appropriate corrective actions are implemented
- Incidents which do not require reporting
    - Medication vials which are discolored, broken, or expired that have not been tampered with may be disposed of using the EMS Medication Disposal Policy.