



**MONTGOMERY COUNTY
FIRE AND RESCUE SERVICE**

21-05AM

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Controlled Medication Use and Security

07/13/2018

Issued by: Fire Chief Scott Goldstein

Policy Number: 21-05AM

Authority: Montgomery County Code Section 21-3 (b)

Supersedes: Policy and Procedure 21-05, *Controlled Medication Use and Security Procedures*, dated March 10, 2005

Effective Date: August 1, 2018

SECTION 1. Purpose:

This policy updates the controlled medication accountability procedures for MCFRS EMS providers to conform to requirements provided in Section 1301.75(b) of the Code of Federal Regulations (CFR). To fully comply with the CFR, it is the intent of MCFRS to be able to account for every vial of controlled medication, in real-time and at any point in time, from ordering to administration (or disposal).

SECTION 2. Applicability:

This policy applies to all MCFRS personnel (career, civilian and volunteer). It was developed in cooperation with the International Association of Fire Fighters Local 1664 and Montgomery County Volunteer Fire Rescue Association.

SECTION 3. Background:

These provisions apply to the initial stocking, security, use, storage, inspection, disposal, re-stocking, expiration, rotation, audit, loss, and accountability of controlled medications. The Controlled Substance Act of 1970 requires that all controlled medications be tracked by an unbroken chain of possession, from the manufacturer to the patient, with a signature required at each step. Accurate record keeping is imperative in this process.

SECTION 4. Definitions:

- a. ALS: Advanced Life Support, describing any person(s) or emergency medical services unit providing advanced life support services, or the equipment designated for such care.
- b. ALS Unit: Any transport unit, suppression unit, light duty vehicle, or assigned group of personnel that includes a Paramedic and a set of ALS equipment.
- c. Controlled Medication (Record) Log: The documentation used to record the nature and amount of controlled medications for ALS Units from one shift to another shift. Effective August 1, this log will be available in a secure on-line environment and will be signed electronically.
- d. Controlled Medication Administration Record: The document used to record MCFRS-required



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information regarding the administration of a controlled medication. Effective August 1, 2018, this record will be available in a secure on-line environment and will be signed electronically.

- e. Controlled Medication: Medications designated by MCFRS as requiring security and accountability, in accordance with Schedule 1-5 of the United States Drug Enforcement Agency (DEA) guidelines.
- f. Paramedic Chase Unit (PCU): An automobile, such as an SUV or a sedan, used to transport a Paramedic and ALS equipment, but does not have patient transport capability.
- g. PMIC: Abbreviation for Paramedic in Charge, the designated paramedic who is in charge of patient care on an MCFRS ALS Unit.
- h. Primary ALS Unit: A unit designated by the Fire Chief as a "controlled" ALS Unit on a full-time continuous basis.
- i. Seal: An individually-numbered, tamper-evident, pull-tight plastic seal. The control numbers of issued seals are on file with the EMS Duty Officer, and is also recorded on the Controlled Medication Log.
- j. Secondary ALS Unit: A unit designated by the Fire Chief as a controlled ALS Unit on a part-time basis.
- k. Specialty ALS Unit: A Paramedic bike team, Paramedic golf cart, or other designated delivery method for ALS service.

SECTION 5. Policy:

It is the policy of the MCFRS to ensure the safe use, accountability, storage, security, and replacement of Controlled Medications, in compliance with requirements provided in Section 1301.75(b) of the Code of Federal Regulations.

SECTION 6. Responsibility:

It is the responsibility of all MCFRS EMS Providers to be accountable for Controlled Medications entrusted to their care. It is the responsibility of the MCFRS EMS Section to ensure that this policy is followed and adhered to, and to report diverted, lost or stolen controlled substances to local, state, and federal authorities in accordance with COMAR and CFR 1301.75(b).

SECTION 7. Procedure:

- a. Purchase/Storage/Provision of Controlled Medication Supplies: Only the MCFRS Medical Director may authorize the purchase of Controlled Medications. The central supply of Controlled Medications will be secured on MCFRS property.
- b. Initial Stocking of ALS Units: The EMS Duty Officer will issue Controlled Medications and Seals to ALS Units as needed to meet the minimum amounts required to provide patient care. These quantities will be determined by the EMS Section Chief, in consultation with the



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MCFRS Medical Director.

1. Seals for these Controlled Medications must be assigned to each ALS Unit with its medication delivery. The EMS Duty Officer must record the Seal numbers in the Controlled Medication Log.
 2. The EMS Duty Officer will issue Controlled Medications to Specialty ALS Units on a temporary basis, for a specific event only. When that event is over, the remaining issued Controlled Medications must be returned immediately to the EMS Duty Officer.
 3. MCFRS Paramedics must not seek, nor can they accept, Controlled Medications or Seals from any source other than the MCFRS EMS Duty Officer. This includes, but is not limited to, hospitals, commercial pharmacies, private physician's offices, or other ALS Units.
- c. Controlled Medication Security and Use:
1. The EMS Duty Officer will assign a unique control number to each vial of all Controlled Medications before assigning them to an ALS Unit.
 2. All Controlled Medications must be stored in a heavy-duty, clear plastic container, with an eyelet installed and used for Seal placement. This plastic container must always be secured with a tamper-evident, numbered plastic Seal.



3. At each shift change, or at any other time the PMIC of an ALS Unit changes, the on-coming PMIC must inspect the Controlled Medications on the ALS Unit. The Controlled Medications in the plastic box must be counted without removing the numbered Seal. The PMIC must electronically sign the Controlled Medication Log, ensuring that the count and the Seal numbers are accurate. Whenever the Paramedic signs for a quantity of a Controlled Medication, he/she acknowledges the responsibility for the security, handling, use, and record keeping for that medication.
4. When a Paramedic needs to use a Controlled Medication on an incident, the Seal must be broken to open the box. The Paramedic should make every effort to use the vial with the



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nearest expiration date. Marking methods, such as using a highlighter, can be used to indicate this.

5. The expiration dates on all vials must be checked whenever the plastic Controlled Medication box is opened.
 6. The administering Paramedic must complete the on-line Controlled Medication Administration Record by completing the information for the corresponding Controlled Medication to document its use. The Controlled Medication amounts and vial number(s) must also be recorded in the eMEDs (or successor system) report.
- d. Restocking an ALS Unit:
1. If the Controlled Medication count on an ALS Unit drops to the predetermined minimum, the PMIC must contact the EMS Duty Officer immediately to restock the Controlled Medications and Seals. Seals must be kept with the issued medications.
 2. An ALS Unit whose supply of Controlled Medications is exhausted must be placed out-of-service until the unit is restocked or released by the EMS Duty Officer. The Controlled Medications stored in the EMS Duty Officer's ALS bag may be used on an ALS incident, or to restock other ALS Units.*
- *Under extraordinary circumstances (e.g., Disaster Level operations) Controlled Medications may be reallocated by other ALS Units for immediate use. This action must be approved only by EMS Command.
- e. Expired Controlled Medications: Controlled medications with expired dates must not be used. A Paramedic who finds an expired Controlled Medication must contact the EMS Duty Officer immediately. The EMS Duty Officer will take possession of the expired medication and return it to the central supply for eventual disposal.
1. If a Controlled Medication has an expiration date consisting of a month/year format (e.g., 05/03); the medication is considered to expire on the last day of that month.
 2. When practical, an EMS Duty Officer may rotate Controlled Medications with imminent expiration dates from a Secondary ALS Unit to a Primary ALS Unit. A Paramedic must not rotate Controlled Medications from one ALS Unit to another without the direct authorization of an EMS Duty Officer.
- f. Controlled Medication Inspection/Audit: The PMIC must verify Controlled Medication control numbers and expiration dates each time the Seal is broken on the Controlled Medication container.
1. EMS Duty Officers may perform periodic, unannounced inspections or audits of Controlled Medications, Seals, and Controlled Medication Logs.
 2. EMS Duty Officers are authorized to confiscate all Controlled Medications, Controlled Medication Logs, and Controlled Medication Administration Records reasonably suspected to be non-compliant with this policy.



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- g. Lost or Damaged Medication Vials and Discrepancies in a Controlled Medication Log: Any indications that a tamper-evident Seal has been breached, that an attempt has been made to do so, or that undocumented changes have been made to the numbered Seals, must be reported to the EMS Duty Officer and the Station Officer immediately.
1. Controlled Medications discovered to be missing or damaged during a shift change, or any discrepancies found in the Controlled Medication Log or Controlled Medication Administration Record must be reported immediately to the Station Officer and the EMS Duty Officer.
 2. A Paramedic who breaks a vial, or accidentally removes the tamper-evident Seal from one of the vials, must contact the EMS Duty Officer immediately for appropriate investigation.
 3. Any evidence of potential criminal action will initiate a formal investigation, including referral to the appropriate law enforcement agency.
- h. Procedures for Secondary ALS Units: The Controlled Medication box will be sealed and kept in the center or the right exterior compartment of the ALS bag. If the unit is not in-service as a full-time ALS Unit, a Paramedic or BLS provider will check the Seal number as part of the daily unit check to verify that there has been no unauthorized access, and he/she will complete the Controlled Medication Log. Any suspected security breach must be reported immediately to the Station Officer and EMS Duty Officer.
- i. Security when ALS Units are Placed Out-of-Service: An ALS bag must never leave the station, or the control of MCFRS personnel, when the unit is placed out of service. If the vehicle is leaving the control of MCFRS personnel, the ALS bag must be removed and placed in a secure location, e.g., the station watch office, or the Station Officer's office. ALS bags must not be left inside vehicles that are routinely parked outside (this does not include response to emergency incidents or the carrying out of MCFRS routine business activities).
- j. Performance Measures: The EMS Section will perform an audit of accountability documentation on a quarterly basis to ensure compliance. This information will be forwarded to the MCFRS EMS Section Chief, MCFRS Medical Director, and the MCFRS Medical Review Committee. The EMS Section will perform an annual policy review to measure this policy's effectiveness. This information will inform structured changes to reflect the current practice.

SECTION 8. Cancellation:

This policy cancels and replaces MCFRS Policy and Procedure 21-05, Controlled Medication and Security Procedures, dated March 10, 2005.

SECTION 9. Attachments:

None.



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Approved:

A handwritten signature in black ink that reads "Scott Gold".

Fire Chief

July 13, 2018

Date