



Division 05

Emergency Medical

Chapter 18 – Advanced Life Support (ALS) Controlled Substances

March 2009

POLICY

This General Order establishes procedures, as mandated by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Controlled Substances Act), to maintain security of controlled substances. Any Fire/EMS Department Advanced Life Support unit assigned controlled substances shall adhere to this General Order.

DEFINITIONS

Controlled Substance – A drug or chemical substance whose possession and use are regulated under the Controlled Substances Act.

Schedule – Controlled substances are divided into five schedules based on their potential for abuse, accepted medical use, and accepted safety under medical supervision

- Schedule II (Morphine Sulfate) – These drugs are only available by prescription, and distribution is carefully controlled and monitored by the DEA.
 - The drug or other substance has a high potential for abuse.
 - The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
 - Abuse of the drug or other substances may lead to severe psychological or physical dependence.

- Schedule IV (Diazepam) – These drugs are available only by prescription, though control of wholesale distribution is less stringent than Schedule II drugs.
 - The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
 - The drug or other substance has a currently accepted medical use in treatment in the United States.
 - Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Suitable Witness – a third party that is affiliated and is authorized to sign for controlled substances on behalf of the receiving facility.

PROCEDURES

1. General Provisions

The Department of Justice, specifically the Drug Enforcement Administration, is responsible for the enforcement of the Controlled Substances Act. The Controlled Substances Act requires "all persons who manufacture, distribute or dispense any controlled drug provide effective controls and procedures to guard against theft and diversion of controlled substances." The Act further requires "all persons who manufacture, distribute or dispense any controlled drug keep inventories and maintain



complete and accurate records of all drugs manufactured, dispensed, obtained, or disposed of."

This General Order applies to any and all medications that have been designated in the schedules of addictive medications ("schedule") by the Controlled Substances Act. The Maryland Medical Protocol for Emergency Medical Service Providers allows for the use of the following "schedule" drugs:

- Morphine Sulfate (Schedule II)
- Diazepam (Schedule IV)
 - "Valium"

These drugs are carried in a prescribed method to reduce the potential for medication dosage errors and tampering. Controlled substances carried on Prince George's County Fire/EMS Department Units shall be as follows:

Morphine Sulfate:

- Concentration: 10 mg/1 ml
- Total Quantity: 2
- Total Dosage: 20 mg

Diazepam:

- Concentration: 10 mg/2 ml
- Total Quantity: 2
- Total Dosage: 20 mg

In all cases, the drug packaging must provide a tamper evident seal to show if someone has accessed the drug. Common examples are sealed medication vials and sealed Carpuject® syringes. Any other form or concentration is not acceptable.

2. Security

Controlled substances are secured by two methods at all times. The primary method to secure controlled substances is always:

1. Mechanical Lock – All controlled substances must be kept secured by a lock at all times.

The secondary means includes the transfer of custody for either:

1. Human Control – Custody of keys is maintained in the possession of an EMS provider at all times.
2. Medication Seal – Custody of the medications is controlled by a tamper-evident and serial numbered medication seal. The number found on the seal is documented as the provider's name.

If any of the security methods are not effective or damaged, immediately contact the appropriate EMS Supervisor for either key or lock replacement. Appropriate Loss/Damage forms will be required.

3. Transfer of Custody

Custody and accountability for controlled substances must be maintained at all times. When custody of assigned controlled substances is transferred, both the person accepting custody and the person relinquishing custody must inspect and verify the controlled substances.

INSPECT:

- The ampule, vial, or Carpuject® syringe shall be inspected for proper volume, damage, and evidence of tampering. It should have proper packaging that would prevent drug tampering.

VERIFY:

- The manufacturer's lot number and expiration date should match the unit log. If the expiration date only indicates the month and year, the



medication expires on the last day of the month.

DOCUMENT:

- Once inspected and verified, the person accepting custody and the person relinquishing custody must document the transfer of the controlled substances in the unit logbook. Both persons will print and sign in the appropriate area to acknowledge the medications are transferred in good order.

A “Custody of Controlled Substances” stamp is issued to each unit that is issued controlled substances. This tool documents each transfer between providers.

If the stamp is not available, the following standard format is utilized:

CUSTODY OF CONTROLLED SUBSTANCES		
DATE		TIME
TRANSFERRED FROM		
TRANSFERRED TO		
MS#1	LOT	EXP
MS#2	LOT	EXP
VALIUM#1	LOT	EXP
VALIUM#2	LOT	EXP

If the unit is dispatched on an incident prior to the proper transfer of the controlled substances has been completed, the person who has current documented custody must respond on the incident.

Once custody is accepted, the person accepting custody is responsible for maintaining the security of the controlled substances until custody is transferred as outlined above.

At no time will transfer of controlled substances occur during an incident that will delay patient care or transport. Transfer should occur after the completion of an incident.

4. Documentation of Waste

When a controlled substance is used during patient care, the provider administering the medication should draw up only the amount to be used on the patient. At the receiving facility, the remainder of the medication must be wasted while being witnessed by hospital clinical personnel. If the provider administering the medication does not transport the patient to a hospital, then the remainder of the medication must be wasted while being witnessed by the EMS Supervisor.

A Controlled Substance Form (Form#1) shall be completed, witnessed, and signed by the provider in custody of the controlled substances. This form is forwarded through the chain-of-command to the AEMS Office.

5. Replacement

Controlled substances are replaced using the procedures outlined in Attachment 1 – Controlled Substance Replacement Procedures.

- Procedure A – If controlled substances can be replaced at the receiving facility.
- Procedure B – If controlled substances cannot be replaced at the receiving facility.
- Procedure C – If controlled substances were administered and the patient was transported by another unit, such as an



ALS transport unit or Medevac Helicopter.

- Procedure D – If expired, damaged, or lost controlled substances need to be replaced.

When a controlled substance is used on an incident, or replaced for any other reason, the replacement dose must be documented in the unit logbook. Included in the documentation will be the manufacturer's lot number and expiration date

Example:
0845hrs 6 mg Morphine Sulfate used on Incident #08-123-0123, replaced at Southern Maryland Hospital, new lot # 56789 exp. 9/02 signature/credentials.

When an EMS Supervisor replaces a controlled substance on a unit they document in the unit logbook the reason for the replacement and the manufacturer's lot number and expiration date.

Example:
0900hrs Morphine Sulfate replaced by EMS801 due to medication expiration. New lot # 98765 exp. 10/08, signature/credentials.

The signature/credentials of both EMS Supervisor and person taking custody of the controlled substance must be documented.

The EMS Supervisor proceeds to Prince George's Hospital Emergency Department and secure a prescription/order from the attending physician. The replacement medications are obtained from the Prince George's Hospital Pharmacy following steps 4-7 of Procedure A of the Controlled Substances Replacement Procedures.

6. Transfer Discrepancies, Loss/Damage, or other issues.

If the person accepting custody of the controlled substances is not comfortable with the condition of the controlled substances, he/she should not accept custody. The EMS Supervisor should be contacted immediately and the problem(s) should be identified.

The person with current custody of the controlled substances remains on-duty until all discrepancies are resolved.

Summaries of all reports of "problems" involving controlled substances will be forwarded via the chain-of-command to Major of AEMS.

If at any time, a medication is destroyed, damaged, lost, or appears to have been tampered with the appropriate EMS Supervisor is to be notified immediately.

Upon notification, the unit is placed out of service and the EMS Supervisor will make arrangements to have an immediate "with cause" urinalysis performed on any person who had access to or custody of the controlled substances. A Loss/Damage report should be completed and forwarded through the chain-of-command. The controlled substance is replaced using Procedure D in Attachment 1.

REFERENCES

N/A

FORMS/ATTACHMENTS

Form 1 – Request for Narcotic Replacement and Verification of Narcotic Waste Form

Attachment 1 – Controlled Substance Replacement Procedures



CONTROLLED SUBSTANCE FORM

VERIFICATION OF WASTE					
Date		Unit		Incident	
Patient					
Receiving Facility					
Controlled Substance		Administered		Wasted	
Morphine Sulfate					
Diazepam					
WASTED BY		PROVIDER SIGNATURE		PRINTED	
WITNESSED BY		SIGNATURE		PRINTED	

REQUEST FOR REPLACEMENT					
Date		Unit		Incident	
Patient				Medical Record #	
Controlled Substance		Dispensed			
Morphine Sulfate		Max 2		10 mg/1 ml	
				LOT	EXP
Diazepam		Max 2		10 mg/2 ml	
				LOT	EXP
RECEIVED BY		PROVIDER SIGNATURE		PRINTED	
DISPENSED BY		PHARMACY REP		PRINTED	

Original: Prince George's County Fire/EMS Department
Pink: Dispensing Pharmacy

CONTROLLED SUBSTANCE REPLACEMENT PROCEDURES

PROCEDURE A	
FACILITIES THAT REPLACE CONTROLLED SUBSTANCES	
Laurel Regional Hospital	Prince George's Hospital Center
Doctor's Community Hospital	Southern Maryland Hospital
Anne Arundel Medical Center	Washington Adventist Hospital
REPLACEMENT PROCEDURE	
<ol style="list-style-type: none"> 1. Present Controlled Substance Form (Form #1) and remaining medication (if any) to receiving facility nurse. 2. Waste remaining medication with <u>suitable witness</u> and obtain witness signature on Controlled Substance Form (Form #1). 3. Replace medications from Emergency Department if possible. If unable then secure prescription/order from the attending/consulting physician. 4. Report to Pharmacy with Fire/EMS Department Photo Identification and request controlled substances from Pharmacy Staff. 5. Verify proper drug, dose, and concentration. 6. Document Lot Numbers and Expiration Dates on Controlled Substance Form. 7. Upon returning to quarters, document new Lot Number(s) and Expiration Date(s) and Incident # where the medication was used in the unit log book. 	

PROCEDURE B	
FACILITIES THAT DO NOT REPLACE CONTROLLED SUBSTANCE	
Washington Hospital Center/MedSTAR	Children's National Medical Center
Providence Hospital	United Medical Center
Bowie Health Center	Holy Cross Hospital
CIVISTA	Howard County General
REPLACEMENT PROCEDURE	
<ol style="list-style-type: none"> 1. Present Controlled Substance Form (Form #1) and remaining medication (if any) to receiving facility nurse. 2. Waste remaining medication with <u>suitable witness</u> and obtain witness signature on Controlled Substance Form (Form #1). 3. Advise appropriate EMS Supervisor through Public Safety Communications that the unit will remain out of service to replace critical equipment. 4. Contact EMS Supervisor to replace Controlled Substances. EMS Supervisor will meet unit and replace medications and document replacement in unit log book as outlined in the General Order. If EMS Supervisor is committed to an emergency incident or the unit is closer to Prince George's Hospital. <ol style="list-style-type: none"> a. Report to Prince George's Hospital Emergency Department. b. Secure prescription/order from the <u>attending/consulting physician</u>. c. Report to Prince George's Hospital Pharmacy with prescription and Fire/EMS Department Photo Identification. d. Verify proper drug, dose, and concentration. e. Document Lot Numbers and Expiration Dates on Controlled Substance Form (Form #1) 5. Upon returning to quarters, document new Lot Number(s) and Expiration Date(s) and Incident # where the medication was used in the unit log book. 	

PROCEDURE C
CONTROLLED SUBSTANCES WERE ADMINISTERED AND THE PATIENT
WAS TRANSPORTED BY ANOTHER UNIT
REPLACEMENT PROCEDURE

1. Advise appropriate EMS Supervisor through Public Safety Communications that the unit will remain out of service to replace critical equipment.
2. Contact EMS Supervisor to replace Controlled Substances. EMS Supervisor will meet unit and replace medications and document replacement in unit log book as outlined in the General Order.
 - a. Present Controlled Substance Form (Form#1) and remaining medication (if any) to EMS Supervisor.
 - b. Waste remaining medication with EMS Supervisor and obtain EMS Supervisor (witness) signature on Controlled Substance Form (Form#1).
3. If EMS Supervisor is committed to an emergency incident or the unit is closer to Prince George's Hospital.
 - a. Report to Prince George's Hospital Emergency Department.
 - b. Present Controlled Substance Form (Form #1) and remaining medication (if any) to facility nurse.
 - c. Waste remaining medication with suitable witness and obtain witness signature on Controlled Substance Form (Form #1).
 - d. Secure prescription/order from the attending/consulting physician.
 - e. Report to Prince George's Hospital Pharmacy with prescription and Fire/EMS Department Photo Identification.
 - f. Verify proper drug, dose, and concentration.
 - g. Document Lot Numbers and Expiration Dates on Controlled Substance Form (Form #1)
4. Upon returning to quarters, document new Lot Number(s) and Expiration Date(s) and Incident # where the medication was used in the unit log book.

PROCEDURE D
EXPIRED, DAMAGED, OR LOST CONTROLLED SUBSTANCES NEED TO
BE REPLACED
REPLACEMENT PROCEDURE

1. Advise appropriate EMS Supervisor through Public Safety Communications that the unit will remain out of service to replace critical equipment.
2. Contact EMS Supervisor to replace Controlled Substances. EMS Supervisor will meet unit and replace medications and document replacement in unit log book as outlined in the General Order.
3. Present Controlled Substance Form (Form #1) and remaining medication (if any) to EMS Supervisor.
4. Waste remaining medication with EMS Supervisor and obtain EMS Supervisor (witness) signature on Controlled Substance Form (Form #1). If medication was lost then document which Lot Number(s) and Expiration Date(s) were lost on Controlled Substance Form (Form#1).
5. Upon returning to quarters, document new Lot Number(s) and Expiration Date(s) in the unit log book.