



GENERAL ORDER

GENERAL ORDER 322.02

Controlled Substances

EMERGENCY SERVICES BUREAU

Issue Date: December 04, 1997

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1 APPLICABILITY

2 All Personnel

3 POLICY

4 The Howard County Department of Fire and Rescue Services (Department) shall establish and
5 maintain guidelines for the administration, use, and management of Controlled Substances (CS)
6 in the pre-hospital environment. These guidelines shall meet or exceed Maryland and Federal
7 laws and standards. As these standards vary based upon the schedule assignment of each
8 individual CS, the Department shall utilize a uniform standard administered in accordance with
9 the strictest guidelines. Maryland Medical Protocols for EMS Providers (MMP) utilizes only CS
10 in schedules II-V, so physical security and accountability measures shall meet Schedule II
11 requirements through MedVaults and vehicle locks.

12 DEFINITIONS

- 13 ➤ **Audit** – a process for thoroughly accounting and inspecting all CS within a field box or
14 safe.
- 15
- 16 ➤ **Controlled Substances (CS)** – Drugs and other substances that are considered CS under
17 the Federal Controlled Substances Act (CSA). These drugs are divided into five
18 schedules according to their medical use and potential for abuse. The Department
19 currently utilizes several CS as prescribed by the Maryland Medical Protocols (MMP).
- 20
- 21 ➤ **Controlled Substances Standard Use** – Standard Uses for CS include those prescribed by
22 MMP and the Department’s Office of the Medical Director (OMD) for pre-hospital
23 patient care. Standard Use shall also include:
 - 24 ○ Waste of unused and/or expired medication(s).
 - 25 ○ Inventory management procedures, as outlined in this general order.
- 26
- 27 ➤ **Crew Member** – term for personnel that have access in Operative IQ.
- 28
- 29 ➤ **Diversion** – Diversion of a CS is the use of a drug for any purpose other than its Standard
30 Use. This shall include removal of the drug from its packaging for any purpose other
31 than its Standard Use.



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- 32 ➤ **Field Box** – a sealable container containing CS.
- 33
- 34 ➤ **Knox MedVault™** – Electronic safe used by the Department to store CS for use in pre-
- 35 hospital care. The product is approved by MIEMSS and the Department for CS storage.
- 36
- 37 ➤ **Safe** – a term used in Operative IQ to describe a virtual location in Operative IQ used to
- 38 house controlled substances when not assigned to a crew member.
- 39
- 40 ➤ **Security Seal** – a cable tie-style fastener used to seal a field box; each security seal will
- 41 have a unique number that are pre-entered into Operative IQ.
- 42
- 43 ➤ **Tampering** – Tampering with a CS is defined as unauthorized, usually surreptitious,
- 44 access to or manipulation of a CS with the intent to gain unlawful access to the drug for
- 45 the purpose of Diversion or tainting.
- 46
- 47 • **Transfer** – the term used by Operative IQ to describe transitioning responsibility of CS
- 48 from one ALS crew member to another.

49 PROCEDURES

50 GENERAL MEDICATION STORAGE/SECURITY PROCEDURES:

51 The following general storage and security procedures shall apply to all CS:

- 52 • The Medical Director and the Fire Chief, or designee, have the authority to determine
- 53 which personnel, Emergency Medical Services (EMS) units, suppression units, and other
- 54 operational elements shall carry CS.
- 55 • All CS shall be stored in a securely locked and substantially constructed container
- 56 approved by the ESB, that complies with state and federal standards and shall only be
- 57 accessed for Standard Use.
- 58 • All EMS transport units shall be fitted with Knox MedVaults for this purpose. MedVaults
- 59 are approved by MIEMSS.
- 60 ○ CS that are stored in a MedVault do not require a secondary seal on the
- 61 MedVault itself.
- 62 ○ CS otherwise stored shall be secured behind two different locks, accessible by
- 63 designated personnel only.
- 64
- 65 • Any time CS are removed from the designated storage locations for distribution or
- 66 standard use, the medications shall be secured by the authorized and individually
- 67 responsible crew member on their person.
- 68 • All Advanced Life Support (ALS) crew members authorized to function in Howard County
- 69 shall be issued a Personal Identification Number (PIN) for Knox MedVault access.
- 70 ○ The Emergency Services Bureau (ESB) shall maintain an active roster of all
- 71 assigned PINs.
- 72 ○ The ESB shall audit this roster every 12 months.
- 73 ○ ESB and OMD may reissue new PINs as determined necessary based upon the
- 74 needs of the Department.



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- 75 ○ Crew members shall keep PIN codes confidential and not share PIN codes with
- 76 anyone.
- 77 ○ Willful violation with the intent to compromise security safeguards is considered
- 78 a serious policy infraction. In addition, this could result in legal consequences.
- 79 ○ ALS crew members shall notify their MDO if they suspect their PIN has been
- 80 compromised.
- 81
- 82 ● All CS shall be removed from the apparatus when that unit is out of service or the
- 83 unit is to be stored outside.
- 84 ○ CS removed from these units shall be stored either with an MDO, the EMS1
- 85 closet MedVault, the quartermaster, or another in-service transport unit.
- 86 ○ When the unit has staffing, CS can then be transferred (see below).
- 87

CS INVENTORY MANAGEMENT:

88 CS Inventories are managed on three levels:

- 89 1. Administrative – ordering, receiving, re-packaging for distribution and initial tracking.
- 90 2. Supervisory – storage and management of field supplies.
- 91 3. Crew Member – Standard Use.
- 92

93 Each level of CS Inventory Management follows a process that allows for positive accountability

94 for CS from purchase through its administration or waste. Each step in the process serves an

95 accountability purpose that is designed to maintain security and protect the patient, the crew

96 member, the Department, and the County while meeting or exceeding state and federal

97 regulations.

98

99

100 Crew members entrusted with the use and management of CS shall abide by the processes

101 established by the Department and outlined in this General Order.

102

EXPIRING CS:

103 MDOs will retrieve CS from field boxes that are expiring and physically move them to the EMS1

104 closet MedVault. This will be documented in Operative IQ.

105

106

107 An administrator will transfer the expiring/expired CS from the EMS1 closet MedVault to the

108 Quartermaster (QM). Expired CS will be kept at the QM.

109

110 All expired CS will be sent to a vendor for final destruction through “reverse distribution.” This

111 process shall occur at least twice a year.

112

113 Documentation of the CS destruction will be completed in Operative IQ.

114

COUNT DISCREPANCY, OPENED, OR POTENTIALLY TAMPERED WITH CS CONTAINERS:

115 Any evidence of CS Tampering or Diversion shall be immediately reported to the OIC, an on-

116 duty MDO, and an on-duty battalion chief. The battalion chief shall notify the ESB Bureau Chief

117 if Tampering or Diversion is suspected.

118



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- 119 • The crew member managing the CS at the time of discovery is obligated to make
- 120 notification as soon as it is safe to do so.
- 121 • It is important to note that the last crew member who signed for the CS is directly
- 122 responsible to report any variances. Failure to report a known discrepancy with CS
- 123 is considered a serious violation of this General Order.
- 124 • Specific instructions for reporting and investigation CS discrepancies are listed in
- 125 Attachment B.

REFERENCES

- 127 • 21 CFR 1301.75 – Physical Security Controls for Practitioners
- 128 • COMAR 10.19.03 – Dangerous Devices and Substances

SUMMARY OF DOCUMENT CHANGES

- 130 Updated to reflect current practices
- 131 Revised discrepancy notification
- 132 Revised crew member transfer procedures

FORMS/ATTACHMENTS

- 134 • Attachment A – Controlled Substance Inventory Management Procedures
- 135 • Attachment B – Controlled Substance Discrepancy Reporting / Investigation Procedures

APPROVED

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Attachment A

Controlled Substances Inventory Management Procedures

The Medical Director and the Fire Chief, or designee, have the direct authority for determining what personnel and operational assets are permitted, or required, to carry and manage CS. Any change to the current list must be approved by the OMD and ESB before the change is implemented.

Chain of Custody for CS:

- CS medications are purchased and received by ESB. Each purchase is directly approved by OMD.
- ESB receives CS in bulk orders and assigns control numbers for individual vials through Operative IQ.
- The control number is used to track each vial through its distribution, use, and removal from the inventory. The control number also allows for ease of identification of lot numbers and receiving patients in the event of a recall.
- MDOs maintain a stock of CS on the MDO vehicles and in approved storage spaces. When needed, ESB shall re-stock the MDOs.
- All transport units and authorized CS carriers shall manage their stock through the MDOs.

Controlled Substance Standard Use & Regular Accounting – Crew Member Level

CS Counts and Inspection:

- The on-duty ALS crew member assigned to the unit with CS shall be responsible for assuring that the CS field box secured with the appropriate security seal is present in the MedVault. The ALS crew member(s) assigned to a station with more than one CS carrying unit shall assure that the CS field box is present in the MedVault secured with the appropriate security seal.

The CS field box shall be transferred and verified between crew members through Operative IQ:

- Daily at shift change; or,
- Any time the assigned ALS crew member for the unit changes.

CS Transfer Procedure

- The Department expects that both off-going and on-coming ALS crew members be present to transfer CS.
- Together the off-going and on-coming ALS crew members shall confirm that the field box and seal number in Operative IQ by physically inspecting the field box in the MedVault.
- If the security seal on the field box matches the information in Operative IQ, then no further inspection of the field box is necessary and the transfer procedure is complete.



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CS Receiving Procedure

- If the off-going ALS crew member cannot be present due to extenuating circumstances such as leaving before the on-coming ALS crew member or on-coming ALS crew member taking an early incident, perform the following procedure to “receive” the CS:
 - The on-coming ALS crew member will utilize the “Receive from Crew” function in Operative IQ.
 - A second uniformed crew member shall be present to confirm that the field box and seal number in Operative IQ by physically inspecting the field box in the MedVault. It is understood that a BLS crew member is not responsible for knowing the use or purpose of a given CS. Their participation in this process is to confirm that there is no obvious tampering or diversion of the security seal.
- In the event of suspected tampering or diversion of the field box and/or security seal, the MDO shall be notified immediately and an audit completed of field box.

CS on BLS / Reserve Ambulances

- Reserve and BLS ambulances that are stocked with CS shall be accounted for daily by the on-coming ALS crew member.
- The on-coming ALS crew member and a witness shall confirm that the field box and seal number match in Operative IQ by physically inspecting the field box in the MedVault. The witness may be an ALS or BLS crew member.
- If the security seal on the field box matches the information in Operative IQ, then no further inspection of the field box is necessary.

Documentation of CS Standard Use

- Standard CS use shall be documented by the ALS crew member in Operative IQ with the required information.
- Waste of CS shall be documented by the ALS crew member in Operative IQ. Waste shall also be documented in Elite to include a witness signature from a uniformed crew member.
- Field boxes shall be resealed with an assigned security seal.

Audits – Field Boxes

- An audit involves opening a field box and confirming that the CS have not been tampered with and that the count matches in Operative IQ.
- An audit shall occur:
 - Every Monday; and,
 - The security seal is missing or detached; or,
 - Suspicion of tampering; or,
 - Randomly directed by ESB.
- A field box audit shall be witnessed by the station officer in Operative IQ.
- Once completed, resealed the field box with an assigned security seal.
- Refer to Attachment B for further guidance if tampering is suspected.



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Audits – MDO Closet MedVault and Quartermaster Stock

- Every Sunday, EMS1 shall audit the contents of the closet MedVault to match in Operative IQ.
- Once a month, the EMS Operations Captain shall audit the contents of the Quartermaster Stock.
- Both of these audits require a second ALS crew member to witness in Operative IQ.

CS Minimum and Maximum Levels

All designated units, approved by the ESB and OMD, shall maintain a par amount of CS. These par levels are dependent upon current Maryland Medical Protocols (MMP), available packaging and EMS program needs. When these levels change, this attachment shall be updated to reflect those changes. Current Par Levels are as follows (represented as minimum-maximum):

- Transport Units: Fentanyl 400-800 mcg; Midazolam 20-40 mg; IM Ketamine 500-1000mg; IV Ketamine 200-400mg.
- Tac Medical: – Fentanyl 200mcg; Midazolam 10mg; IM Ketamine 500mg; IV Ketamine 200mg.
- MDO: IV Ketamine for RSI 500-2000mg; other CS amounts within reason for Standard Use and restock of transport units.
- Special Events Transport Units: Same stock as regular transport units. However, the CS for this unit(s) shall be transferred to an MDO office MedVault when the unit is placed out of service (OOS).

Restock of CS

When a unit hits the minimum par level, they shall notify an MDO for restock. When restocking a field box:

- Restock the CS from the MDO's field box and document loading the field box in Operative IQ.
- ALS crew members will witness loading and resealing of the field box in Operative IQ.

Administrative Processes - Purchasing & Repackaging:

ESB, with the direct approval from the OMD, shall purchase CS from contract vendors as needed to maintain an adequate stock for Department use. Purchased CS should be shipped to a location that is authorized by OMD and equipped to immediately secure the CS in accordance with the requirements of state and federal law.

Upon receipt, ESB shall package the CS from their bulk packaging into individual vials for field use.

- Each CS vial shall have a unique label and sealed in a manner so that tampering is evident.

Once packaged, ESB shall maintain accountability of the CS until it is needed for restock in the field.



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Attachment B

Controlled Substance Discrepancy Reporting / Investigation Procedures

Any discrepancy involving controlled substances (CS) is a serious matter and must be reported immediately and resolved as soon as possible. This appendix identifies procedures for addressing several discrepancy types as well as incidents of suspected tampering and/or diversion. It should be noted that the chain of custody for the CS begins with the last crew member to account for CS until the next crew member signs for them.

Immediate Notification Requirements

Any of the following require immediate notification to the station OIC, MDO, and battalion chief. The battalion chief shall notify the ESB Bureau Chief if tampering or diversion is suspected.

- Any evidence of CS tampering or diversion; or,
- Vials that are found opened or tampered with; or,
- Any suspicion of missing or diverted medication; or,
- Other suspicious activity.

CS Accounting Discrepancies

In the event the CS count or vials present do not match what is listed in Operative IQ, the discovering crew member shall follow the immediate notification process. The affected unit may be placed out of service until the matter can be investigated by an MDO. The off-going responsible crew member should be contacted immediately to assist with the investigation.

- The MDO shall do the following:
 - Sequester all of the CS in question.
 - All sequestered items are placed in its container and secured in the MDO vault.
 - Obtain photographs of the medication in its packaging to illustrate the shortage.
 - Provide replacement CS medications to bring the unit to par levels.
 - Obtain memorandums from, at minimum, the discovering crew member(s) and the off-going responsible crew member. The MDO shall thoroughly document the proceedings in a memo, as well.
- The MDO shall ensure that the station OIC is aware and then immediately notify each of the following:
 - The on-duty battalion chief
 - The ESB EMS Executive Battalion Chief or Captain.
 - The Office of the Medical Director.
- The MDO shall follow up with submission of all written documentation in real time.
- The ESB shall coordinate with the OFC and OMD regarding next steps, to include possible notification of law enforcement and regulatory authorities, as appropriate.



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Tampering/Diversion

As part of every CS accounting process, crew members shall inspect CS containers for evidence of tampering and/or diversion. Crew members should suspect tampering if any seals or caps are damaged or broken on a CS. The medication should look the same in all containers of that CS type. Tampering and diversion are crimes and must be reported immediately. The following is similar to the accounting discrepancy procedure but is specific to the tampered/diverted containers:

- The MDO shall do the following:
 - Sequester all of the CS in question.
 - All sequestered items are placed in its container and secured in the MDO MedVault.
 - Obtain photographs of the medication in its packaging for illustration.
 - Provide replacement CS medications to bring the unit to par levels.
 - Obtain memorandums from, at minimum, the discovering crew member(s) and the off-going responsible crew member. The MDO shall also thoroughly document the proceedings in a memo.

- The MDO shall ensure that the station OIC is aware and then immediately notify each of the following:
 - The on-duty battalion chief
 - The ESB EMS Executive Battalion Chief or Captain.
 - The Office of the Medical Director.

- The ESB shall facilitate the investigation by:
 - Notifying Howard County Police Department (HCPD) and obtain a case number and contact and provide any supporting materials requested.
 - Initiating an activity audit of the MedVault on the affected unit.
 - Compiling any patient care records (PCR) for the effected unit from the time of discovery back to the last time the CS were confirmed to be normal and attempt to identify any undocumented, legitimate, standard use.
 - If appropriate, working with Maryland State Police Forensics to test the CS in question.

- The OMD shall provide oversight and assure accountability, as applicable:
 - Notify MIEMSS.
 - Notify Maryland Department of Health.
 - Notify DEA.
 - Oversee the investigation and assure State and Federal compliance.

Upon completion of any investigation, sequestered CS may be repackaged and redistributed or wasted/destroyed, as appropriate for the situation. ESB and the OMD shall determine the appropriate disposition for each instance.