



OMD Clinical Administrative Policy

Controlled Substances

Draft for Review and Approval 9/14/2022,
Effective 10/1/2022; all prior versions
Review Before 3/2024

Purpose

To provide security and accountability for controlled substances utilized in the out-of-hospital treatment of patients. Emergency Medical Services Authority and/or Fire Department personnel shall adhere to all state and federal legal requirements for obtaining, securing, storing, distributing, inventorying, administering, and destroying controlled substances.

A. Ordering

1. The Controlled Substances Officer shall notify the Office of the Medical Director of the need to order any controlled substances.
2. The Office of the Medical Director shall prepare the appropriate DEA prescription receipt/form for the review and signature of the Chief Medical Officer (registrant).
3. Once signed by the Chief Medical Officer (registrant), the DEA receipt/form will be forwarded to the Controlled Substances Officer to place the order.

B. Receiving Orders

1. The Controlled Substances Officer shall deliver DEA forms to vendor(s).
2. The Controlled Substances Officer shall receive orders as follows:
 - a) Order(s) will be inventoried by two individuals.
 - b) Verified inventory is entered in the Master Controlled Substances Log.
 - c) Totals and a Signature/Initials will be placed on the DEA receipt/form.
 - d) The Office of the Medical Director will retain a photocopy of the signed DEA 222 form.
 - e) The DEA receipt/form of the completed order will be retained by the agency at the address of the DEA number agency, after the order is received along with a copy of the receiving slip. Copies of the packing slip shall be kept on file with each agency.
 - f) Office of the Medical Director approved tracking labels will be placed on each individual controlled substance.
 - (i) In a prefilled syringe the label should be placed over the distal end of the syringe and the proximal end of the protective cap in a manner that the label must be broken in order to remove the cap.
 - (ii) In a vial the label should be placed over the protective cap in a manner that the label must be broken in order to remove the cap.
3. All controlled substances shall be kept in controlled and secured areas.
 - a) The location of the controlled substances shall be within an Office of the Medical Director approved location for each indicated agency.
 - b) Overstock shall be kept within a locked area, secured within a non-carryable safe, and reflected in the Master Controlled Substances Log.
 - c) Controlled substances, meant for distribution to paramedics at the start of their shift, shall require two locks operated by different keys or key codes for access.
 - d) These substances shall be placed within a locking box within a cabinet affixed to/within the response apparatus.



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- e) The Controlled Substances Officer and his/her assistant shall have direct access to controlled substances security cabinets and lock boxes.
- f) Overstock shall be kept separate and apart from the normal day-to-day inventory available for distribution to the paramedics and accessible only by the Controlled Substances Officer, his/her assistant, Chief Medical Officer (registrant), and/or Chief Medical Officer designee(s).

C. Transfer of Controlled Substances between EMSA Divisions and/or agencies

- 1. There will be no transfer of controlled substances between EMSA Divisions, EMSA Substations and/or agencies unless under special circumstances and only after approval by the Office of the Medical Director.
- 2. A written request for such transfer of controlled substances shall be forwarded to the Office of the Medical Director specifically indicating the rationale for the transfer. Acceptable rationales include a vendor's inability in filling prescription(s) beyond local agency control and either natural or man-made disaster that prohibits the usual delivery and/or receiving of controlled substances. If such transfer of controlled substances is granted, the transaction will be posted in the Master Controlled Substances Log in addition to any applicable state and DEA forms.
- 3. Receiving order guidelines will apply when accepting transferred controlled substances.

D. Distributing Controlled Substances to Paramedics & Related Documentation.

- 1. The Controlled Substances Officer or his/her assistants shall be the only individual(s) to distribute resupply stock.
- 2. All individual controlled substances will be vacuum sealed prior to being placed in the control substances lock boxes. During the vacuum sealing process a unique identifiable sticker (approved by the Chief Medical Officer) should be adhered to the inside of the vacuum sealed package prior to sealing to ensure integrity of the packaging.
- 3. The Controlled Substances Officer shall review the available inventory for the ambulance or paramedic-staffed fire apparatus-controlled substances lock boxes.
- 4. Stock levels of controlled substances to be carried on each ambulance: 4 containers of fentanyl (usual concentration of 100 mcg/container); 2 containers (usual concentration of 4 mg/container) of morphine sulfate; 4 containers of midazolam (usual concentration of 10 mg/container); 2 containers of diazepam (usual concentration of 10 mg/container).
- 5. Stock levels of controlled substances carried on each paramedic-staffed fire squad, engine, or truck: 2 containers of fentanyl (usual concentration of 100 mcg/container); 2 containers of morphine (usual concentration of 4mg/container); 2 containers of midazolam (usual concentration of 10 mg/container); 2 containers of diazepam (usual concentration of 10 mg/container).



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6. The stock levels of controlled drugs on each individual ambulance and paramedic-staffed fire apparatus shall be accurately recorded between shift changes and resupply intervals.

EMSA:

- At shift change, materials management assistant or authorized designee shall be present with paramedic during inventory, inspection, and/or return of controlled substances. Both individuals are to count all controlled substances and agree to inventory status and integrity of containers with signed documentation of such.
- The materials management assistant or authorized designee and paramedic must validate any usages to ensure appropriate documentation as listed in item E.2 (below).
- In the event of tampered/damaged and/or unaccounted controlled substances at any inspection, all involved personnel will remain on-duty and the last authorized personnel will retain custody of the controlled substances until all discrepancies are immediately reported to the supervising EMS officer and an OMD Division Chief with sufficient resolution acceptable to both the EMS officer and OMD Division Chief.

Fire Departments:

- At any paramedic shift change, both off going and oncoming paramedic signatories shall be present for controlled substances inventory and inspection. Both individuals are to count all controlled substances and agree to inventory status and integrity of containers with signed documentation of such.
 - Paramedics must validate any usages to ensure appropriate documentation as listed in item E.2 (below).
 - In the event of tampered/damaged and/or unaccounted controlled substances at any inspection, all involved personnel will remain on-duty and the last authorized personnel will retain custody of the controlled substances until all discrepancies are immediately reported to the supervising EMS officer and an OMD Division Chief with sufficient resolution acceptable to both the EMS officer and OMD Division Chief.
7. When resupplying, signatures of both the Controlled Substances Officer or his/her designee and the receiving paramedic shall be placed upon the Master Controlled Substances Log and Apparatus Controlled Substances Log.
 8. All controlled substances shall be placed and maintained (with obvious exception of when being administered to patients) in the vehicle's controlled substances lock box.
 9. Each paramedic shall maintain the Apparatus Controlled Substances Log, recording all controlled substances received and dispensed during their shift. The log shall be kept in a secured place at all times otherwise.



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E. Administration of Controlled Substances by Paramedics & Related Documentation.

1. Controlled substances shall be administered in compliance with the Medical Control Board authorized treatment protocols.
2. Paramedics shall enter the date, time, agency incident number, patient name, clinical condition treated, physician ordering (if applicable), amount administered, and amount discarded (if applicable) and their own name in the Apparatus Controlled Substance Log, ensuring all such entry is printed with legibility for any controlled substance(s) administration and/or opening of controlled substance container(s).
3. The patient care report shall contain the same details as in the Apparatus Controlled Substances Log for any controlled substance(s) administered.
4. All filled individual pages from any Apparatus Controlled Substance Log shall be retained by the Controlled Substances Officer. The information contained on each page shall be transferred to the Master Control Substances Log.

F. Loss of or Destroying Controlled Substances & Related Documentation

1. Any unused portions of controlled substances administered to patients shall be recorded in the Apparatus Controlled Substances Log. The log should bear the signature of two persons attesting to the fact that the drug was disposed. One of two persons should be a receiving physician, nurse, or in the instance of non-transport, a colleague assigned to that same apparatus.
2. If a controlled substance is opened and not administered, the paramedic shall prepare an incident report detailing the rationale. The incident report and the controlled substance shall be turned over to the Controlled Substances Officer or his/her designee to be sent for destruction. The Controlled Substances Officer or his/her designee will log the event and submit the incident report to the Office of the Medical Director.
3. If a controlled substance container is damaged, an incident report shall be prepared by the paramedic involved and/or discovering the damage. The damaged container shall be turned over to the Controlled Substances Officer or his/her designee. The Controlled Substances Officer shall notify the Office of the Medical Director to allow inspection of the container prior to its destruction.
4. If controlled substances are reported as lost, an on-duty EMS supervisor/officer and the Controlled Substances Officer or acting designee shall immediately be notified and the following report(s) made:
 - a) A report shall reflect the details of events regarding the loss.
 - b) The Controlled Substances Officer or appropriate agency designee shall notify the Chief Medical Officer (registrant) or his/her designee before end of shift.
 - c) The Chief Medical Officer (registrant) or his/her designee shall report the loss to law enforcement authorities in accordance with prevailing state and federal requirements.



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- d) Investigation(s) regarding suspected diversion shall be conducted in accordance to directives from the Chief Medical Officer (registrant) and/or law enforcement authorities.

H. Expired Controlled Substances & Related Documentation

1. Expired controlled substance inventories shall not be destroyed by personnel of the Emergency Medical Services Authority, the EMSA contractor or a Fire Department.
2. All expired controlled substances shall be sent for destruction no less frequently than every 180 days and/or whenever the amount of accumulated expired controlled substances exceeds 100 single patient use vials, ampules, prefilled cartridge/syringes, or other formats.
3. Each agency is responsible for completing the DEA form for destruction.
4. Each agency shall forward a copy of the DEA form for destruction to the Office of the Medical Director with the date and name of the person sending the form to the DEA.
5. Prior to sending expired controlled substances for destruction, the Office of the Medical Director shall be notified to schedule an appointment for verification of count.

I. Internal and External Auditing & Related Documentation.

1. The Controlled Substances Officer shall conduct regular audits of all controlled substances, on a schedule approved by the Chief Medical Officer (registrant), and submit all findings for inspection, including expired controlled substance inventories, damaged controlled substances inventories, and used/completed controlled substances log sheets to the Office of the Medical Director.
2. The Office of the Medical Director shall itself conduct a regularly scheduled audit of system-wide controlled substances.
3. All audit documentation shall be placed on file with the Office of the Medical Director and made available to state and federal authorities in accordance with prevailing requirements.

J. Controlled Substance Access:

1. Access to the controlled substance apparatus/ambulance safe and/or box shall be limited to the paramedic, either through a PIN number and/or key. As outlined in Protocol 17I: Controlled Substance Handling & Documentation – Field Paramedics.
2. EMT, EMT-I, AEMT **shall not have** a PIN number and /or key to access the apparatus/ambulance-controlled substance safe and/or box.
3. If the apparatus/ambulance safe is locked out and requires a Fleet Technician to reset the safe, the Fleet Technician shall notify the agency's Narcotic Officer to be available while the safe is being reset and/or open. The agency's Narcotic Officer will then take possession of the controlled substance box within the safe.