

Guideline Name: Controlled Substances		Division: EMS
Effective Date: June 23, 2017	Revised February 22, 2024	Approval(s): Kim Woodward Division Chief

I. Objectives

- To insure proper handling of controlled substance in compliance with State and Federal Law.
- To maintain strict chain of custody of controlled substances.
- To ensure all forms, inventory and documentation of controlled substances is accurately and properly documented.

II. **Scope:** The scope of this SOG includes all system employees, and designees.

III. Procedure

1. General

- A. The EMS Division Chief shall ensure that the State and Federal DEA licenses are valid.
- i. The DEA Certificate of Registration (DEA Form 223) shall be kept in the administration office and shall be readily accessible for official inspection
 - ii. There must be a separate registration for each storage location where controlled substances are distributed.
 - iii. Practitioner registrations must be renewed every three years. Renewal registrations use DEA Form 224a, renewal Application for DEA Registration. The cost of the registration is indicated on the application form.
- B. A modification of registration must be completed if there are any address changes.

2. Annual Inventory of Controlled Substances

- A. EMS Administrators shall perform an inventory of controlled substances by counting all controlled substances on a semi-annual basis.
- i. This shall be completed by matching the central stock located in the Control Room with the recorded inventory; and
 - ii. Physically opening all controlled substances boxes checking the expiration dates and confirming all counts are correct.
 - iii. All medication shall be examined for signs of tampering.
 - iv. All information shall be recorded on a semi-annual inventory control sheet (attached) and shall be kept with the licenses as above.
 - v. Inventory documentation shall be maintained for at least two years from the date that the inventory was conducted.
 - vi. Each inventory must contain the following information:
 - a. Time of inventory
 - b. Actual names of the controlled substances
 - c. Each finished form of the substances, i.e. injectable liquid
 - d. The number of dosage units
 - e. Disposition of the controlled substances.

- B. The controlled substances stock shall be kept secured with at RFID Access panel, key access and RFID into the controlled substances safe.

3. Ordering and Restocking of Controlled Substances

- A. Ordering- The logistics staff officer shall in coordination with EMS Administration will establish stocking requirements, and shall submit the order to the OCES Division Chief who will order replacement stock from the designated source.
- B. A par level shall be established, with a minimum and a maximum.
- C. Logistics Manager notifies the EMS Division Chief and OCES Administrative Assistant when par levels reach the minimum.
- D. Fentanyl orders require completion of The U.S. Official Order Form (Form 222) schedules I & II, and shall be signed by the EMS Division Chief. The Order Form may be submitted via the CESOS process electronically by the EMS Division Chief.
- E. The Form 222 is sent certified mail to the appropriate vendor or submitted electronically. Copies of the completed form are filed separately in the “DEA forms completed folder” and the remaining blank forms are filed in the appropriate vendor’s folder. Forms are kept secure and in a locked box.
- F. Acquiring Supply – The person receiving the controlled substances shipment must initial the appropriate line of form 222 and is returned to the folder.
- G. All deliveries of controlled substances shall be inspected, the packing slip or invoice initialed and retained in the office of the Administrative Assistant. Schedule II orders require that Form 222 is initialed and is retained in the appropriate folder.
- H. Controlled substances shall be locked, securely in the Administrative Assistant's office until they are entered into stock. No other tasks shall be performed until supplies are securely locked away.
- I. Stocking – Controlled substances shall be entered into stock with a dual verification and the inventory count shall reflect the following, at the time of stocking:
 - i. Amounts entered into stock and
 - ii. Finished form of substances
 - iii. The number of dosage units of each finished form
 - iv. Expiration dates
- J. After verifying a proper accounting of stock, all controlled substances shall be locked securely in the controlled substance box located in the secure storage room in the Control Room.
- K. Logistics or EMS Administrator shall complete and sign the appropriate drug inventory form attesting that the information listed therein is correct and the form is retained in the electronic asset inventory system.

4. Restocking and Routine Inventory Procedure

- A. In addition to documenting the administration of the controlled substance on the electronic patient care report, Paramedics shall accurately and completely document every controlled substance administration on the "Controlled Substance Administration" Form.
- B. Paramedics shall document the drug box identifier in the electronic patient care report in the appropriate field for every controlled substance administration.
- C. After the administration of a controlled substance the Paramedic will reseal the controlled substance box with a "red tag" seal that is electronically documented through Operative IQ. The "red tag" is a visual cue that the controlled substance box is missing the normal contents.
- D. Upon transferring the controlled substance box to an EMS Battalion Chief both parties will conduct a dual verification that the documentation pertaining to the disposition of controlled substance is complete and bearing the appropriate signatures on the "Controlled Substance Administration" Form.
- E. In the instance that an EMS Battalion Chief is unable to access the necessary documentation he or she shall initiate investigation into the chain of custody of the drug box and notify the EMS Division Chief or designee.
- F. An electronic report of the usage/waste forms shall be generated and emailed to all EMS Battalion Chiefs and Administrators on a weekly basis through Operative IQ.
 - i. The EMS Administrator and Logistics personnel shall perform a count of the specific controlled substance confirming documented inventory. This is conducted every time a controlled substance box is restocked.
 - ii. The EMS Administrator and Logistics Officer shall then restock the controlled substance, and document:
 - a. CFS number
 - b. Box identifier
 - c. Date
 - iii. The Quality Assurance Coordinator will ensure all information is correct and accurate for complete quality assurance tracking of controlled substances. An electronic report named "Controlled Substance Master Log" will be generated weekly and compared with Patient Care Records for accuracy. This report will be signed and uploaded as a PDF and placed in a folder on the EMS Shared Drive under "Controlled Substance QA."
- G. Controlled substance boxes shall be refilled with the standard amounts of medication and shall be identical except for their unique identification label, verified by the EMS Administrator or Logistics Officer restocking the individual box.
- H. The individually labeled controlled substance boxes will be sealed with a unique seal number confirmed by an EMS Administrator and Logistics personnel.

- I. Spare boxes not assigned to field personnel shall be stored under double lock in the controlled substance cabinet, with exception of the spares carried by the on duty Battalion Chief. (See K. below)
- J. Every Monday an EMS Administrator or Logistics personnel shall count all drug boxes that are kept in the controlled substance safe, verifying the boxes' security seal integrity is not in question and boxes are not expired.
- K. Every shift the on duty Battalion Chief shall generate an electronic report named "Controlled Substance Box Location Report" that identifies the controlled substance box carried by each paramedic in the system. This report should be utilized to assure that all controlled substances boxes in the system are accounted for and has all appropriate documentation has been completed. After this has been completed the report can be discarded.
- L. Battalion Chiefs may carry up to four controlled substances boxes in the double locked Battalion Chief's vehicle. Battalion Chiefs must maintain electronic accounting of these boxes at all times.
- M. If the electronic system is not functioning, documentation for controlled substances will be completed utilizing written forms that shall be maintained as a backup system. These documents will be logged electronically when the electronic system regains full function.

5. Wastage and/or Breakage Procedure

- A. If there is breakage, spillage, or routine wastage of the controlled substances a "Controlled Substance Administration" Form must be accurately and thoroughly completed. This form is located electronically in the electronic asset system.
- B. Expired controlled substances shall be removed from stock and placed in the expired drugs receptacle in the controlled substances inventory box. The Drug Destruction unit of DHHS shall be notified by calling 919-733-1765. Documentation created upon the DHHS visit shall be maintained for a period of two years.
- C. When there is medication left over after administration, the medic shall dispose of the drug in front of a second medical professional in the sink with running water or in a sharps box filled with absorbent. The wastage shall be documented and must have the witness's electronic signature through the electronic asset system.

6. Loss or Theft of Controlled Substances

- A. Upon discovery of loss or theft of controlled substances, the paramedic shall notify the on-duty Battalion Chief. The EMS Operations Manager and the Department Director must also be notified.
- B. If Loss or Theft occurs an Incident Report form must accompany the "Controlled Substance Administration" Form explaining all details of the occurrence. This form is located electronically in the electronic asset system.
- C. The Division Chief shall notify Human Resources for the administration of an employee drug test and follow-up with notification to the Department Director.

- D. Law enforcement shall be notified if theft is suspected.
- E. The Operations Manager shall complete all required DEA loss report documentation (Federal form 106). This form shall be submitted to DEA and to the DHHS office in Greensboro. The forms shall be attached to any police report and shall be maintained in the administrative office.
- F. If the controlled substances are found after the filing of the form 106, then a letter stating the outcome shall be attached to the 106 and sent to both agencies. The reporting law enforcement agency shall also be notified.
- G. The Department Director will be kept current on all available information pertaining to said loss or theft, via the chain of command.

7. Daily Operations Transfer Procedures

- A. Daily operation ambulances may be assigned two controlled substance boxes.
- B. The off-going Paramedic shall transfer their controlled substances over to the oncoming paramedic or the oncoming paramedic may initiate a "pick up" in the electronic inventory system. Peak load paramedics may transfer the controlled substance box back into stock on the "Transfer Form". The paramedic is responsible for the documentation of the disposition of the box at the beginning and end of every shift. The documentation shall include the following:
 - i. date of transfer;
 - ii. time;
 - iii. location of transfer;
 - iv. box identification;
 - v. contents of the box;
 - vi. whether or not the box was sealed;
 - vii. Seal number and
 - viii. Paramedic's electronic password and pin serving as their signature.
- C. The controlled substance "Transfer Form" shall be kept electronically through electronic inventory asset system. EMS Battalion Chiefs shall be responsible for assuring that personnel complete the "Transfer Form" correctly and in a timely manner through generating the "Controlled Substance Box Location Report." These forms can be found in the electronic asset system.
 - i. When transferring from person to person on shift change, a timely manner is considered within 30 minutes.
- D. When possible, controlled substances shall be signed over to the on-coming paramedic and witnessed by the off-going paramedic. In rare instances, the shift Battalion Chief may authorize an EMT-Basic to accept and sign for controlled substances or may accept possession of same.
- E. Upon receipt of a controlled substances box, paramedics shall inspect the assigned box to ensure that the medications are intact, within their expiration date and the box is sealed with the correct seal number. The paramedic shall record the findings on the "Transfer Form." Any discrepancies are to be reported immediately to the EMS Battalion Chief who shall then notify the EMS Division Chief or designee. An "Incident Form" is to be filled out in detail.

- F. It is the paramedic's discretion whether to keep a controlled substance box on their person or locked in a double locked compartment of the ambulance. Ultimately, it is the responsibility of the paramedic to ensure the availability of medication during patient contact.
- G. The EMS Battalion Chief will be automatically notified when a controlled substance is used via electronic submission from the inventory system documentation. At a minimum the paramedic shall have in their position adequate controlled substances for one patient per current EMS Protocols.
- H. Paramedic shall not have an unsealed controlled substance box in the field except in extreme circumstances and the, only with prior arrival from the on duty Battalion Chief. The Battalion Chief should make every attempt to deliver additional seals to the Paramedics to assure that controlled substance boxes are always sealed.
- I. If the off-going paramedic fails to physically transfer the controlled substances, the EMS Battalion Chief shall be notified by the incoming medic and the off-going paramedic shall be contacted and shall return the controlled substances box immediately.

8. Special Event Transfer and Volunteer Medic Transfer Procedure

- A. The on-duty Battalion Chief shall make arrangements for controlled substances transfer for special events to ensure security is maintained and proper accounting of boxes is ensured.
- B. Based on the amount needed, the EMS Battalion Chief will obtain the proper number of boxes from the safe, conduct a documented transfer, and physically hand off the box to the receiving paramedic.
- C. Following conclusion of the special event, the EMS Battalion Chief ensures the boxes are sealed and medication accounted for. The Battalion Chief conducts a documented transfer and transfers the box physically to the safe and documents transfer to the safe in the electronic inventory system.