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| REGION 11 CHICAGO EMS SYSTEM POLICY | Title: Controlled Substance Requirements |
| | Section: Patient Care |
| | Approved: EMS Medical Directors Consortium |
| | Effective: December 6, 2023 |

CONTROLLED SUBSTANCE REQUIREMENTS

I. DEFINITIONS

- A. Controlled Substance: A drug whose manufacture, possession, or use is regulated by the government. Controlled substances for use by EMS in Region 11 include the following drugs:
1. Fentanyl
 2. Midazolam
- B. Drug Enforcement Agency (DEA): Federal organization in charge of enforcing the controlled substance laws in the United States.

II. REGULATIONS

- A. Controlled Substance Act (CSA): Federal law that regulates substances with the potential for abuse or dependence.
- B. Protecting Patient Access to Emergency Medications Act (PPAEMA): Amends the federal Controlled Substance Act to provide guidance around the administration of controlled substances by EMS agencies and EMS personnel.

III. RESPONSIBILITIES OF EMS AGENCIES

- A. Drug Enforcement Administration (DEA) Registration
1. Each EMS agency and licensed EMS vehicle functions administratively under a Resource Hospital in an EMS System as defined in the system plan.
 2. These EMS agencies are registered under the Resource Hospital and are supplied controlled substances under the hospital pharmacy.
- B. Use of Standing Orders or Protocols
1. EMS personnel can administer a controlled substance as defined by EMS Protocols.
 2. EMS personnel can also administer a controlled substance after a verbal order by the EMS Medical Director or after consultation with Online Medical Control.
- C. Storage of Controlled Substances
1. Only controlled substances on the Region 11 Drug, Equipment, and Supply (DES) List shall be carried by EMS vehicles.
 2. Controlled substances should be stored in a securely locked, substantially



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constructed cabinet or safe that cannot be readily removed.

3. Controlled substances shall be stored with the ability to examine for tampering, expiration dates, and counts.
4. EMS agencies may store controlled substances in EMS vehicles used by the agency.
5. EMS vehicles that are out of service should have their controlled substances secured and accounted for per agency policy.
6. If controlled substances are removed from the cabinet or safe, they should remain under the paramedic's direct supervision at all times.

D. Access to Controlled Substances

1. Access to controlled substances should be limited to crew members authorized to utilize the medication during the course of patient care and those responsible for inventory.
2. All access to controlled substances should occur in the presence of two personnel.

E. Documentation

1. Every use of controlled substance shall be documented in the patient care record as well as on a Region 11 controlled substance accountability form.
2. Every access to controlled substances, whether for shift change count and examination or restocking, shall be documented with a beginning and ending count on an inventory form.
3. All documentation shall have two signatures.
4. All documents shall be securely stored for a period of two years.

F. Use of Controlled Substances

1. After each use of a controlled substance, the following should be documented on the patient care report:
 - a. Medication used
 - b. Amount used
 - c. Amount wasted
 - d. Patient name
 - e. Patient address
 - f. Date given
 - g. Time given



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h. Initials of Paramedic administering the controlled substance

2. Any amount of a controlled substance that is not administered to the patient and that is remaining in the vial should be brought to the hospital to be wasted. This process needs to be witnessed by at least two people (one paramedic and one hospital personnel) and recorded on the controlled substance accountability form.
3. After use, the entire stock of the controlled substance that was accessed should be counted by two personnel and the counts documented on the inventory form.
4. In the event that a controlled substance is administered by a non-transport EMS vehicle, the transporting EMS vehicle may exchange their stock of the same controlled substance vial with the non-transport EMS vehicle. The non-transport EMS vehicle should document the medication administration on the patient care report and both EMS vehicles should update their inventory records with the new lot number and expiration date.

G. Restocking EMS Vehicles at Hospitals

1. Following an emergency response, EMS agencies may restock their EMS vehicles with the controlled substance used from the receiving hospital.
2. For each use, a controlled substance accountability form should be completed by the paramedic and a hospital representative.

H. Accountability

1. At the start of every shift, all controlled substances must be examined for evidence of tampering, expiration dates, and counts.
 - a. Counts shall be verified against the last count.
 - b. Amount, concentration, and expiration date should be verified.
 - c. Medication vials should be visually inspected for evidence of tampering.
2. Documentation of the daily inventory of controlled substances must have two signatures for accountability.
3. Any damage, loss, or expired medication should be reported immediately to the EMS vehicle's supervisor and assigned Resource Hospital EMS Coordinator in verbal and written format.

I. Maintenance of Controlled Substance Records

1. EMS agencies must maintain records for each controlled substance administered or disposed of in the course of providing emergency medical services.
2. This includes the medication name, concentration, amount administered, patient



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name and incident number.

3. Records are required to be maintained for at least two years.

J. Expiring Controlled Substances

1. Each EMS vehicle is assigned to a Resource or Associate Hospital for exchange of soon to expire controlled substances.
2. Within seven calendar days of expiration, the EMS vehicle should report to their assigned hospital with the controlled substance and request an exchange.
3. Exchange will only occur at assigned hospitals and within the defined dates and hours on the Region 11 Expiring Controlled Substances Exchange Assignments list– see Appendix

K. EMS Agency Liability

1. EMS agencies are liable for ensuring the proper use, maintenance, reporting, and security of controlled substances used by the agency.
2. Each EMS agency should have an internal policy that defines and verifies controlled substance accountability.
3. EMS personnel should be trained in controlled substance accountability standards and policies.

IV. RESPONSIBILITIES OF ALL HOSPITALS

- A. Each hospital will maintain an internal policy regarding replacement of controlled substances for EMS.
- B. Each hospital will maintain a record of each controlled substance restocked for EMS after field administration as documented in the patient care report.
- C. Each hospital will accept any residual controlled substances or waste from EMS personnel after patient care and dispose of it according to existing hospital and Drug Enforcement Agency (DEA) policy.
- D. After EMS submits the controlled substance accountability form, which documents the medication dose and concentration administered, the hospital will then replace the controlled substance according to the Region 11 Drug, Equipment and Supply (DES) List.
- E. If the hospital does not have the exact amount and concentration as listed on the Region 11 DES list, the hospital should NOT restock the EMS vehicle and refer them to their Resource Hospital.



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F. Any damage, loss, or expired doses requires immediate verbal and written notification of the Resource Hospital EMS Coordinator.

V. ADDITIONAL RESPONSIBILITIES OF RESOURCE HOSPITALS

- A. If the receiving hospital is unable to restock an EMS vehicle, the Resource Hospital will be responsible for restocking the medication.
- B. Cases of damage, loss, tampering, or expired medication shall be handled at the Resource Hospital.
 - 1. The incident will be investigated per internal hospital policy by the Resource Hospital EMS Coordinator and the EMS Medical Director. Findings will be forwarded to IDPH.
 - 2. A replacement will be issued to that vehicle by the Resource Hospital.
 - 3. An investigation and report must be completed by the ambulance service provider with conclusions or outcomes forwarded to the Resource Hospital and IDPH.



Region 11 Expiring Controlled Substance Exchange Assignments

EMS vehicles may only exchange controlled substances within 7 calendar days of expiration date as assigned and detailed below.

Any missing doses, expired doses, or suspected tampering will be handled at the Resource Hospital per the Region 11 Controlled Substance Requirements Policy.

Chicago South EMS System #1113

University of Chicago Medicine

- CFD Ambulances: 1, 14, 24, 30, 35, 36, 38, 55, 57, 72, 78
- CFD Engines: 47, 50, 54, 60, 73, 84, 120, 122, 129
- CFD Mass Casualty Bus 8812
- ATI/Vandenburg Ambulance
- Hawthorne Racetrack Ambulance

Process for Exchange

CCD Building (main hospital) Pharmacy 2nd floor
Monday-Friday 10am-2pm

Advocate Trinity Hospital

- CFD Ambulances: 5, 9, 22, 25, 29, 37, 50, 51, 60, 70, 71, 76, 79
- CFD Engines: 46, 62, 72, 74, 82, 93, 97, 126
- CFD Truck: 40

Process for Exchange

See Pharmacy for exchange
Monday-Friday 6:00am – 9:00pm

Holy Cross Hospital

- CFD Ambulances: 8, 12, 17, 18, 21, 27, 49, 54, 58, 75
- CFD Engines: 64, 88, 115, 116, 123, 127
- CFD Trucks: 41, 45, 60,

Process for Exchange

Emergency Department
Monday-Friday 9:00am – 3:00pm

Mount Sinai Hospital

- CFD Ambulances: 23, 33, 34, 69, 77, 80
- CFD Engines: 38, 113
- CFD Truck: 32

Process for Exchange

Emergency Department
Monday-Friday 10:00am – 6:00pm

Chicago Central EMS System #1108

Northwestern Memorial Hospital

- CFD Ambulances: 11, 41, 42, 74
- CFD Engines: 1, 2 (Boat), 4, 13, 39, 98
- CFD FAS Boat 688, 689
- Event Medical Solutions
- MASE

Process for Exchange

9th floor Pharmacy Feinberg Building
Monday-Friday 8:00am – 4:30pm

Rush University Medical Center

- CFD Ambulances: 19, 45, 68
- CFD Engines: 23, 26, 49
- CFD Truck: 2

Process for Exchange

Emergency Department
Monday-Friday 9:00am – 3:00pm



Region 11 Expiring Controlled Substance Exchange Assignments

EMS vehicles may only exchange controlled substances within 7 calendar days of expiration date as assigned and detailed below.

Any missing doses, expired doses, or suspected tampering will be handled at the Resource Hospital per the Region 11 Controlled Substance Requirements Policy.

Chicago North EMS System #1103

Advocate Illinois Masonic Medical Center

- CFD Ambulances: 6, 32, 40, 61,
- CFD Engines: 71, 78, 124
- CFD Truck: 12
- Lifeline Ambulance

Process for Exchange

See Pharmacy for exchange
Monday-Friday 9am-5pm

St. Joseph Hospital

- CFD Ambulances: 13, 31, 56
- CFD Engines: 55, 59, 83, 102

Process for Exchange

Emergency Department
Monday-Friday 9:00am – 3:00pm

St. Mary & Elizabeth Medical Center

- CFD Ambulances: 3, 44, 52, 64
- CFD Engines: 30, 43, 57, 76
- CFD Truck: 36

Process for Exchange

Emergency Department
Monday-Friday 9:00am – 3:00pm

Community First Medical Center

- CFD Ambulances: 7, 20, 46, 47, 48, 63
- CFD Engines: 68, 91, 108, 125
- CFD Truck: 58

Process for Exchange

No Restrictions - 24/7 Emergency Department

Resurrection Medical Center

- CFD Ambulances: 2, 16, 26, 39, 59, 73
- CFD Engines: 9, 10, 11, 12, 79
- CFD Truck: 55
- CFD Tower Ladder: 63

Process for Exchange

No Restrictions - 24/7 Emergency Department
See ED Nurse/EMS Coordinator for exchange

Lurie Children's Hospital

- CFD Ambulances: 4, 28, 43, 53, 62, 66
- CFD Engines: 8, 19, 29

Process for Exchange

Emergency Department
Monday-Friday 9:00am – 3:00pm

Chicago West EMS System #1178

Stroger Hospital of Cook County

- CFD Ambulances: 10, 15, 65, 67
- CFD Engines: 18, 34, 95, 99, 117
- CFD Truck: 29
- CFD SLD: Special Ops, Surge Ambulances 150-151-152-153-154-155-156-157-158-159
- Hatzalah

Process for Exchange

By Appointment Only, Call 312-864-1291
Monday-Friday, No Holidays