LEGAL and REGULATORY REQUIREMENTS: The procurement, prescribing, administration, and transfer of CS are highly regulated by federal and state laws and regulations, as well as compliance standards (Joint Commission and Centers for Medicare and Medicaid Services). The possession and administration of controlled substances is governed by the U.S. Department of Justice Drug Enforcement Administration. This policy establishes the EMS standards for management of Controlled Substances (CS) by NWC EMSS agencies, hospitals, and personnel in accordance with Federal DEA Rules and Regulations. The Federal Rules are found in the Code of Federal Regulations (Title 21 CFR, Part 1300-1399), the Controlled Substance Act, and Public Law 115–83 Nov. 17, 2017 131 STAT. 1267 Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA). See the DEA website. www.deadiversion.usdoj.gov

DEA REGISTRATION: The DEA requires that each site that stores or dispenses CS be registered. Before 2017, an EMS agency was authorized to administer CS under the DEA registration of the EMS medical director overseeing the agency's patient care. Language added by PPAEMA now allows EMS agencies to receive their own DEA registration to administer controlled substances.

DEFINITIONS

CONTROLLED SUBSTANCES: Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. See Table 1. CS, as approved for EMS administration in the NWC EMSS, include fentanyl, morphine, ketamine, midazolam, diazepam, and others as approved by the EMS MD.

Use of Standing Orders: The PPAEMA allows EMS agencies to "*administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional*." To do so, the EMS agency must 1) be authorized to do so by state law and 2) have a standing order or verbal order from a medical director or an authorizing medical professional.

Id. § 823(j)(4); "**Medical director**" is defined as a physician registered with the DEA to administer controlled substances and who provides medical oversight to an EMS agency. See 21 U.S.C § 823(j)(13)(H) (2017).

"**Standing order**" is defined as "*a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances" to EMS patients.* See 21 U.S.C § 823(j)(13)(M) (2017).

"**Verbal order**" is defined as "an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional." See 21 U.S.C § 823(j)(13)(N) (2017).

I. POLICY

A. All drugs approved for distribution to EMS agencies and administration to EMS patients shall be procured, deployed, stored, inventoried, clinically administered, documented, restocked, and records kept in compliance with laws, rules, regulations, and policies and procedures that govern EMS drug oversight and administration.

B. EMS personnel licensed, credentialed, and authorized to access or handle CS are educated and competent in established policies, procedures, and regulatory requirements.

C. CS are stocked in as ready-to-use form as possible and in the lowest commercially available units frequently given to EMS patients. Inventory is routinely evaluated for opportunities to reduce the need to waste.

D. The System advocates for a collaborative and interdisciplinary approach to and accountability for CS diversion prevention and response within the System that supports a culture of safety for patients and healthcare workers.

E. Under no circumstances may any drug or pharmacologic deployed to an EMS agency be diverted for personal purposes or use by EMS personnel unless the recipient is logged as a patient and is being treated by appropriate EMS personnel and care is documented in the electronic medical records reporting system.

F. **EMS Agency Liability**. EMS agencies under the EMS MD's supervision, are liable for ensuring the proper use, maintenance, reporting, and security of CS used by the agency. Before the PPAEMA, liability regarding use of CS by an EMS agency was placed on the DEA-registered medical director or the hospital overseeing the agency.

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that--

1. *all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;*
2. *the recordkeeping requirements are met with respect to a registered location and each designated location of the agency;*
3. *the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with* the storage subsection*;* and
4. *the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted* (NWC EMS protocols and policies).

II. PROCEDURES – Administrative requirements, oversight, accountability, operational flow

A. **PROCUREMENT:** Controlled substances will be issued by the assigned System hospital to each new EMS ALS vehicle as it is approved for operation within the NWC EMS System per the inventory levels listed on the Drug and Supply List for ambulances and EMS Policy M9: MedENGINES for Alternate response vehicles.

B. **DRUG ADMINISTRATION:** ALS EMS personnel may administer approved CS outside the physical presence of a medical director or authorizing medical professional in the course of providing EMS care in compliance with the NWC EMSS SOPs.

1. Label all CS drawn up into syringes, if not immediately administered, with the drug name and dose withdrawn, and the initials of the healthcare worker (HCW) who drew up the drug written on the label.
2. Keep syringes containing CS under the direct control of the person preparing the syringes until administration to the patient.
3. When sequential doses are required from a single syringe, document the doses given as separate entries in the ePCR. Each PCR shall be signed by 2 ALS personnel.
4. Note the amount wasted (if applicable) in the ePCR and at the hospital.

C. **STORAGE and SECURITY**

1. EMS agencies may store CS in the agency location registered with the DEA, unregistered locations, and in EMS vehicles (as defined below) used by the agency under circumstances that provide for security of the CS consistent with the requirements established by regulations of the Attorney General.
2. ***EMS vehicles may store controlled substances if they are***
   a. *situated at a registered or designated location of the agency; or*
   b. *in an emergency, the EMS vehicle used by the agency is:*
      (1) *traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or*

(2) *otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General* and NWC EMSS Policies and Procedures.

The United States Attorney General must be notified of all unregistered locations at least 30 days before the CS are initially delivered to those locations.

3. **Storage in DRUG BAGS:** ALS Agencies may store approved CS in a "drug bag". However, the container of CS must be stored separately from non-controlled substance drugs and be secured using a device such as a tamper detectable plastic tie lock. ALS personnel must be in control of the bag containing CS at all times when not secured in a locked location on the EMS vehicle or in the Agency Station as described below.

4. **Storage in EMS VEHICLES**: CS must be stored in a secure fashion in a "substantially constructed tamper resistant locked cabinet" with 24 hour/day accountability to prevent diversion or tampering. CS shall be stored with the ability to examine for tampering, expiration dates, and inventory counts. EMS Agencies are encouraged to consider, but are not mandated, to use technology such as the CyberLock Access Control System that records all openings of the locked cabinet and creates an audit report to confirm the person who has accessed the CS. See https://cyberlock.com. Access to EMS vehicles shall be limited. They shall be occupied or locked and keys removed whenever deployed outside of quarters. EMS quarters shall be locked or have secured limited access.

D. **Additional SECURITY controls**

1. In order to minimize the opportunities for theft or diversion of CS, EMS agencies have an obligation not only to provide effective physical security, but also to initiate additional procedures to reduce access by unauthorized persons.

2. **Access:** The EMS Agency/Registrant must limit access to CS to a minimum number of authorized employees.

   a. **Controlled substances may be accessed by ALS EMS personnel.** The Agency/Registrant may designate other individuals to access controlled substances but the designation must be in writing identifying the individuals granted access.

   b. All **access shall occur in the presence of two personnel** authorized by the Agency/registrant. All **access shall be recorded and witnessed**. (Daily Controlled Substance Log signatures; medication cross-check documented in ePCR).

   c. Individuals authorized by the Agency/Registrant can pick up and transport CS. Incidental contact by EMTs helping the ALS personnel carry equipment while on scene is allowed but the ALS practitioner must be in control of access to these medications at all times.

3. **Recommendation:** Although not specifically required by Federal law or regulation, the following additional security measures are recommended to enhance overall security: Change all CS container lock combinations or passcodes upon termination of any employee with knowledge of the combination(s), regardless of the reason for the termination.

4. **Out-of-Service:** EMS vehicles that are out-of-service (inoperable, not available for current operation, no crew available, not functional) shall have their CS removed, secured and accounted for per the Agency medication management plan. This does not apply to an ambulance that is OOS secondary to the crew having lunch, completing reports or other duties, which prevent temporary response to calls.

5. **CS on Non-EMS vehicles prohibited:** "Jump bags" (bags carried by personnel in their personal or Agency vehicles not listed in the Agency's EMS Plan with IDPH) shall only carry drugs or supplies that are sold over the counter. No CS may be stored in personal or Agency non-EMS vehicles or on personal property.

E. **MONITORING and SURVEILLANCE:**

1. **Daily Accountability for CS Inspections, LOGS, and Record keeping**:
The System will perform a variety of audit processes to identify inventory discrepancies and the possible diversion of CS.

2. The DEA has defined three basic requirements regarding CS records:

   a. Records should be readily retrievable.

   b. Records should be kept for two years.

   c. Records should be available for DEA inspection in an efficient and business-like manner and in a sequence that can be easily reviewed on site or back at DEA offices. Orderliness, legibility, and a format compatible with a copy machine are important.

3. EMS agencies must follow **record requirements** stated in the CS Act. These requirements include recording all CS that are received, administered, or otherwise disposed of and storing records in the locations where CS are received, administered, and discarded.

   Such records ``*(i) shall include records of deliveries of controlled substances between all locations of the agency; and ``(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of."*

4. Each Agency must maintain an **unbroken chain of custody** and internal controls as evidenced by a **fully completed Controlled Substance Log** for each EMS vehicle that carries controlled substances. The logs shall be maintained at each registered and designated location of the agency where the CS are stored.

5. **DAILY COUNTS:** At the start of every shift or transition of crew members (if more frequent than daily), all CS shall be visually examined using a double-count process whereby **two different licensed ALS practitioners** with NWC EMSS ALS privileges (preferably one from the off-going and one from the on-coming crew whenever possible) **simultaneously** inspect and count the drugs for comparison to required System inventories, last count numbers, evidence of tampering, and expiration dates. The double-count process is for the protection of the ALS practitioners, both to prevent diversion and to avoid culpability should there be a discrepancy in the count.

6. **CS LOG DOCUMENTATION:** The signatures (written or electronic on the PDF fillable form) of the two ALS practitioners completing the daily CS inspection/count, their legible EMS license numbers, as well as the numeric drug counts must be entered onto the Controlled Substance Log. Note and initial changes in EMS inventories during that shift.

7. **PROCESSING OF CONTROLLED SUBSTANCE LOGS**

   a. **PEMSC Review**: The PEMSC shall review all CS logs for completeness on a periodic basis (best practice model: weekly). At the end of the month, the PEMSC shall inspect the document for completeness, sign, and date their final review.

b. **Missing information:** If documentation is incomplete or missing, the PEMSC shall notify the ALS personnel who are accountable for missing counts/signatures to **append an explanation to the record** as to why an entry was missing. Under no circumstances are signatures to be added on the daily count lines at a later date to amend the record.

c. **Forward to assigned hospital EMSC/educator:** The PEMSC shall forward the log originals and all appended explanations to the agency's designated Hospital EMSC/Educator no later than the 4th week of the following month.

d. **Hospital EMSC/educator review:** The HEMSC/E shall also review the form(s), verify completeness, and sign and date their review. If signatures or counts are omitted without reasonable appended explanation, an RFC shall be forwarded to the PEMSC and agency Chief/ EMS CEO or designee seeking an explanation and improved performance.

e. The original logs with appended explanations, PEMSC and HEMSC/ educator signatures and shall be **electronically archived** at the designated System hospital in accordance with DEA and IDPH procedures (5 yrs for Illinois).

8. **INCIDENT INVESTIGATION and REPORTING:**

Count discrepancies, theft, or loss of CS

ALS personnel shall notify the Provider EMSC, EMS MD, and EMS Administrative Director of all count discrepancies, suspected theft, or loss of any controlled substance immediately upon discovery of such discrepancy, loss or theft. Suspected thefts shall also be reported to local law enforcement agencies.

a. All reasonable avenues will be pursued to account for the missing drug(s). Discrepancies must be resolved within 24 hours of discovery. (Best practice model: within same shift.)

b. **Initiate an RFC:** If an agency experiences a count discrepancy due to loss, theft, or missing CS that cannot be immediately and acceptably explained and resolved, complete a Request for Clarification Form (RFC). The EMS Admin Director can assist the PEMSC in identifying elements that must be included in their internal investigation (e.g., signed statements from all EMS personnel accountable for the chain of custody before and after the drug(s) were missing) and other reporting requirements.

c. Federal regulation requires that registrants **notify the DEA** Field Division Office in their area, in writing, of the theft or significant loss of any CS **within one business day** of discovery of such loss or theft.

(1) The Agency shall complete and submit DEA Form 106, "Report of Theft or Loss of Controlled Substances". (21 C.F.R. § 1301.76(b). See https://apps.deadiversion.usdoj.gov/webforms/dtlLogin.jsp. The EMS MD may need to assist in filling out the report as a DEA # is required.

(2) DEA CS registrants are strongly encouraged to complete and submit the DEA Form 106 online. In addition to being more convenient, completing the form online results in fewer errors.

9. **Evidence of tampering:** If any CS appears to be tampered with or is not sterile and/or ready for patient administration, ALS personnel shall immediately bring the situation to the attention of their Provider EMSC. If the PEMSC is unavailable, they shall notify an EMS agency officer to immediately begin an internal investigation.

Evidence of tampering must also be reported immediately to the EMS MD and EMS Administrative Director.

a. Immediately remove the CS with questionable tampering from vehicle inventories. Note the removal in the CS log and initiate an RFC.

b. Immediately notify the PEMSC or agency supervisor who shall ensure that the drug is brought in its original packaging to the agency's assigned System hospital pharmacy or EMS Coordinator (per hospital policy) for assay, wasting, and restocking. The mode of transport will depend on the Agency's DEA registration status. If not independently registered, the drug must remain under the custody of two paramedics on an agency vehicle documented in the EMS System plan. If independently registered, the drug may be transported by personnel and within vehicles identified in the DEA registration application.

10. **DISCIPLINARY ACTION**: Prohibited behaviors such as a break in the chain of custody of controlled substances, lying or deceit about inventory checks/drug counts; falsification of EMS records, diversion of drugs for personal purposes or use; or two or more instances of an unexplained discrepancy during a practitioner's duty cycle is grounds for disciplinary action by the EMS Agency and/or EMS MD.

III. **PEER TO PEER CS EXCHANGES**

A. An ALS Clinician that opens, prepares, and/or gives a CS from their vehicle's inventory but does not transport the patient may be restocked from another ALS EMS vehicle on scene with ALS clinicians who assume responsibility for the patient and opened CS packages and labeled syringes for transport as long as the exchanged CS meet the packaging, concentration, and dosing specifications as listed in the System Drug and Supply List.

B. **The following shall be verified by two ALS personnel before placing the restock CS into and re-securing the originating vehicle's EMS CS container:** Medication, correct concentration, amount; and expiration date. Ensure that counts are current and accurate against the CS Log. If an equal and appropriate exchange cannot be completed on scene, the ALS clinicians from the vehicle that opened their stock must bring the original open packaging and labeled syringes to the receiving hospital for wasting/exchange per policy.

C. **INTRA-AGENCY Exchange:** The EMS PEER to PEER Mutual Aid Controlled Substance (CS) Restock and Exchange Form is not needed if CS are opened and restocked on scene between two responding vehicles from the same agency (example, ambulance restocks a MedEngine). Complete the exchange as listed in Sections A and B above; and document the incident and all patient care on one ePCR. The transporting ALS clinician shall bring the original opened CS and labeled syringes to the receiving hospital for wasting and exchange per policy.

D. **AGENCY to AGENCY Exchange (mutual aid response):** Complete the EMS PEER to PEER Mutual Aid Controlled Substance (CS) Restock and Exchange Form [FORM] if an ALS clinician from Agency A opens, prepares, and/or gives a CS from their inventory but does not transport and are restocked from Agency B that transports the patient.

1. **Form documentation, imaging, processing of drug exchange:**

a. Complete the exchange as listed in Sections A & B above.

b. ALS clinicians from both agencies shall jointly complete and image the FORM.

c. The transporting agency shall **bring the FORM to the hospital along with the labeled syringe(s) and opened original drug package(s) for wasting and exchange per System policy**.

2. **PCR documentation:**

   a. **NON-TRANSPORTING AGENCY** (that opened, prepared, and/or gave the CS from their inventory) shall complete and post an ePCR attesting to their care within two hours of patient contact. Attach the imaged Peer to Peer Mutual Aid CS Restock and Exchange form to the ePCR.

   b. **TRANSPORTING AGENCY**: Document on their ePCR that a CS was opened, prepared, and/or given (prior to arrival) by another EMS agency ALS clinician. Attach the imaged Peer to Peer Mutual Aid CS Restock and Exchange form to the ePCR.

E. In all cases: Update vehicle inventory tags and Controlled Substance Supplemental Logs

IV. WASTING/EXCHANGE PROCEDURE AT HOSPITALS

A. All hospitals must maintain inventory standards for CS in compliance with DEA and Joint Commission requirements and EMS best practice models.

B. **Restocking EMS Vehicles at Hospitals**. Following an emergency response, EMS agencies may receive CS from a hospital for purposes of restocking without completing CSA order forms provided the following are met:

1. **Exchange:** Labeled syringe(s) and opened original CS drug package(s) are to be given to receiving hospital ED RNs for wasting and exchange with information relative to the patient for whom the drug was opened, prepared, and or given. Syringes and CS containers shall be discarded in limited-access waste containers that render the waste irretrievable and waste procedures shall comply with organizational procedures for waste management.

2. The **Agency/registrant** maintains a record of such exchange where the vehicle is primarily situated (NWC EMSS ePCR and Controlled Substance Logs). The EMS Agency/registrant is required to keep written documentation of this transaction for a period of 5 years.

3. The **hospital** maintains a record of providing CS to the agency: The hospital is required to keep written documentation of this transaction for a period of 5 years.

4. After receiving replacement CS inventory, **the following shall be verified by two ALS personnel before placing into and resecuring the EMS CS container:** Medication, correct concentration, amount; and expiration date. Ensure that counts are current and accurate against the CS Log.

C. **Wasting CS**: If the amount of a CS drug given is less than the prepackaged or prepared dose, the ALS practitioner shall bring in the remaining medication to be appropriately wasted in the presence of an ED nurse per the hospital's policy. CS shall be wasted as close to the time of arrival at the hospital as possible. Any amount of a CS that is wasted shall be witnessed by at least two authorized medical professionals (1 RN and 1 ALS practitioner) and recorded. The name and signature of the nurse witnessing the wastage must be documented in the ePCR and on hospital records per hospital policy. The DEA prefers to have a 3rd party witness when possible, but is not mandatory.

D. **Breakage and Spillage of CS**: Breakage does not constitute a "loss" of CS. When there is breakage, damage, spillage, or some other form of destruction, all recoverable controlled substance must be disposed of according to DEA requirements. **Bring all damaged or broken containers to your assigned System hospital** for disposal. If the breakage or spillage does not allow recovery of the drug, the Agency/registrant must document the circumstances of the breakage in the Controlled Substance log. Two individuals who witnessed the breakage must sign the log indicating what they witnessed.

E. **Returns of Expired CS Drugs**: Controlled substances that are expired or within 14 days of expiration or need to be removed from inventory for any reason cannot be wasted. The Agency/Registrant shall **return the drug to their assigned System hospital for disposal and replacement** in compliance with that hospital's exchange policy and procedure. The hospital will need to request permission from the DEA to dispose of any controlled substance. The hospital shall submit DEA Form 41 at least 14 days in advance of the proposed disposal. The preferred method of disposal is to use a reverse distributor (a DEA registered disposal firm.) Other methods need approval from the DEA District Office.

Table 1 **Schedules of controlled substances**

Schedule	Definitions	Examples
I	High abuse potential with no accepted medical use; medications within this schedule may not be prescribed, dispensed, or administered	Heroin, marijuana, ecstasy, gamma hydroxybutyric acid (GHB)
II	High abuse potential with severe psychological or physical dependence; however, these medications have an accepted medical use and may be prescribed, dispensed, or administered	Morphine, codeine, hydrocodone, hydromorphone, methadone, oxycodone, fentanyl, methylphenidate, pentobarbital
III	Intermediate abuse potential (ie, less than Schedule II but more than Schedule IV medications)	Hydrocodone/acetaminophen 5 mg/500 mg or 10 mg/650 mg; codeine in combination with acetaminophen, aspirin, or ibuprofen; anabolic steroids; ketamine
IV	Abuse potential less than Schedule II but more than Schedule V medications	Propoxyphene, butorphanol, pentazocine, alprazolam, clonazepam, diazepam, midazolam, phenobarbital, pemoline, sibutramine
V	Medications with the least potential for abuse among the controlled substances	*Robitussin AC*, *Phenergan* with codeine

References:

1. Controlled Substances Act of 1970, Pub.L. 91–513, Title II, 84 Stat. 1242.
2. Protecting Patient Access to Emergency Medications Act of 2017, Pub.L. 115-83, 131 Stat. 1267 (amending 21 U.S.C. § 823 (2017).
3. Opioids are used to manage pain in patients suffering from fractures, trauma, and other painful medical conditions. Benzodiazepines are used to stop potentially life-threatening seizures. See Patient Care, QI and General Safety Comm., National Emergency Medical Services Advisory Council, EMS Utilization of Controlled Substances (2017).

21 U.S.C § 823 (2016). The current list of controlled substances can be found on the DEA website or in 21 C.F.R. §1308.

https://www.congress.gov/115/plaws/publ83/PLAW-115publ83.pdf
https://www.cdc.gov/phlp/publications/topic/briefs/ema/index.html

https://www.ems.gov/pdf/Draft-EMS-Utilization-of-Controlled-Substances-011817.pdf

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