# Milwaukee County Emergency Medical Services Controlled Substance Management Plan

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11/17/10
Wisconsin EMS
Controlled Substance Management

Purpose Statement

Establish a standard for accountability and minimum requirements for drug inventory, documentation of usage and replacement of controlled substances in accordance with Federal DEA Rules and State of Wisconsin Regulations. The purpose of these regulations is to deter opportunity for and to recognize episodes of diversion.

Background and Introduction

Products listed with the symbols shown below are subject to the Controlled Substances Act of 1970. These drugs are categorized according to their potential for abuse. The greater the potential, the more severe the limitations are on their prescription.

Products that fall into DEA categories are expressed below:

<table>
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<th>CATEGORY</th>
<th>INTERPRETATION</th>
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<td>CI</td>
<td><strong>High potential for abuse.</strong> No medical value</td>
</tr>
<tr>
<td>CII</td>
<td><strong>High potential for abuse.</strong> Use may lead to severe physical or psychological dependence.</td>
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<tr>
<td>CIII</td>
<td><strong>Potential for abuse less than CI and CII.</strong> Use may lead to low to moderate physical dependence or high psychological dependence.</td>
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<td><strong>Low potential for abuse relative to CIII.</strong> Use may lead to limited physical or psychological dependence.</td>
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<td>CV</td>
<td><strong>Low potential for abuse relative to CIV.</strong> Use may lead to limited physical or psychological dependence, less than CIV.</td>
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Possible controlled substances for use by ambulance providers:

- CII Morphine, Fentanyl, Hydropromorphine
- CIII Ketamine
- CIV Lorazepam, Midazolam, Diazepam

This is not an all-inclusive list, but rather an example of some of the most commonly used medications.

The possession and administration of controlled substances is governed by the U.S. Department of Justice Drug Enforcement Administration as well as the State of Wisconsin Statutes and Administrative Rule as established by the Department of Licensing and Regulation and the Pharmacy Examining Board. The source of Federal
Rule is the Code of Federal Regulations (Title 21 CFR, Part 1300-1399) and the Controlled Substance Act. Wisconsin Rules of significance can be found in Chapter Phar 8.

The CFR and Federal Register can be found at www.gpoaccess.gov/cfr/index.html.

The Practitioner’s Manual may be found at www.DEAdversion.usdoj.gov.

All practitioners that will manufacture, distribute, or dispense controlled substances are required to register with the DEA. The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment (Title 21 CFR 1301.22). For the purposes of Emergency Medical Services, the medical director shall be the registrant and the EMTs will be acting as his agent in administering controlled substances to patients. The medical director will be treating the EMS agency for which he provides oversight as his practice. As such, he is allowed to maintain an inventory of controlled substance for the administration to patients in the usual course of business once registered with the DEA.

Security Requirements

It is often cited that controlled substances need to be secured with a double lock. There are no rules or regulations that require a double lock for storage of controlled substances that are used by a practitioner for treating patients in the course of his usual business. However, security is very important. From the DEA Practitioner’s Manual:

Title 21 CFR Section 1301.71(a), requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances. A list of factors is used to determine the adequacy of these security controls. Factors affecting practitioners include:

1. The location of the premises and the relationship such location bears on security needs
2. The type of building and office construction
3. The type and quantity of controlled substances stored on the premises
4. The type of storage medium (safe, vault, or steel cabinet)
5. The control of public access to the facility
6. The adequacy of registrant’s monitoring system (alarms and detection systems)
7. The availability of local police protection

Practitioners are required to store stocks of Schedule II through V controlled substances in a securely locked, substantially constructed cabinet. Practitioners authorized to possess carfentanil, etorphine hydrochloride and/or diprenorphine, must store these controlled substances in a safe or steel cabinet equivalent to a U.S. Government Class V security container.
Each EMS Service must determine what level of security is necessary. A reasonable minimum is to keep them secured within a vehicle that is also secured or under appropriate surveillance.

Inventory

There are several models on how to stock and re-stock controlled substances for use by EMS. Regardless of the model a system uses, there will always be an inventory of controlled substances within the system. This inventory is the direct responsibility of the registered medical director.

Recordkeeping

Records for Schedule II Controlled Substances must be maintained separately from all other records. Records for Schedules III-V do not need to be separate, but they must be readily retrievable from all ordinary records.

Inventory counting must be done at least once every 2 years and a complete and accurate written, typewritten, or printed record must document controlled substances on hand.

The administration of all controlled substances must be documented to include patient name, patient address, date of administration, name of controlled substance, amount administered, and the initials of the person administering the controlled substance.

Per Federal DEA regulations, all records shall be kept for two (2) years. Wisconsin regulations however require these records to be kept for a minimum of five (5) years.

Disposal (Title 21 CFR Section 1307.21)

Controlled substances that are expired or need to be removed from inventory for any reason cannot be wasted. You need to request permission from the DEA to dispose of any controlled substance. The registrant shall submit DEA Form 41 at least 14 days in advance of the proposed disposal. The preferred method of disposal is to utilize a reverse distributor (a DEA registered disposal firm.) Other methods need further approval from the DEA District Office.

Procedure

1) Storage
   a) Only controlled substance approved by the medical director shall be carried on ambulances.
   b) Controlled substances should be stored in a secure fashion.
   c) Controlled substances shall be stored with the ability to examine for tampering, expiration dates, and counts.
2) Access
   a) Access to controlled substances shall be limited to crew members authorized to
      utilize the medications in the course of usual patient care and those responsible
      for inventory.
   b) Access shall be limited to only those personnel necessary to maintain inventory
      and utilize the medication during patient care.
   c) All access shall occur in the presence of two personnel.

3) Documentation
   a) Every use of controlled substance shall be documented in the patient care record
      as well as on an inventory sheet
   b) Every access to the controlled substances whether for shift change count and
      examination or during restocking shall be documented with a beginning and
      ending count
   c) All documentation shall have two signatures
   d) All documents shall be securely stored for a minimum of five (5) years.
   e) A service needs to determine if the patient care record or if the inventory sheet
      will be the primary record for the DEA. For CII substances, these records need
      to be maintained separately from all other records and the record must have all
      required information (patient name, address, controlled substance, amount
      administered, date administered, initials of person administering substance)

4) Use
   a) After use of a controlled substance the following shall be documented:
      (1) Medication used
      (2) Amount used
      (3) Amount wasted
      (4) Patient name
      (5) Patient address
      (6) Date given
      (7) Time given
      (8) Initials of person(s) administering
   b) Any amount of a controlled substance that is wasted should be witnessed by at
      least two people and recorded.
   c) After use, the entire stock of controlled substance that was accessed shall be
      counted by two personnel and counts documented.

5) Replacement
   a) Controlled substance should be replaced according to department guidelines.
      This also applies to replacement of expired medications.
6) Daily accountability
   a) At the start of every shift, all controlled substances shall be examined for
evidence of tampering, expiration dates, and count.
   i) Counts shall be verified against the last count.
   ii) Any discrepancy or evidence of tampering shall be reported immediately.
   iii) Theft or loss of a controlled substance needs to be reported to the DEA within
1 business day and a DEA Form 106, Report of Theft or Loss, needs to be
completed and submitted.
   iv) Any controlled substance that appears to have been tampered with shall be
secured for DEA investigation, and the DEA shall be notified within 1
business day.

7) Out-of-Service
   a) Ambulances that are out-of-service should have their controlled substances
secured and accounted for according to department policy.

8) Facility Storage
   a) Replacement inventory should be stored in a locked cabinet or locked
refrigerator.
   b) Access should be limited to necessary personnel.

9) Facility Replacement
   a) After receiving replacement inventory, the following should be verified by two
people:
      (1) Medication
      (2) Amount
      (3) Date received
      (4) Current count
      (5) Inspection of entire inventory for tampering and expiration dates

   b) If the replacement inventory was damaged or appears to be tampered with
during shipment a service supervisor should be notified immediately and proper
DEA notification shall be made.
DISPOSAL OF CONTROLLED SUBSTANCES

Section 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports;

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

POLICY: An Emergency Medical Technician - Paramedic is authorized to administer prescription and controlled medications and possess needles, syringes and administration devices as outlined by Chapter HFS 110 of the Wisconsin Administrative Code. The authorization is only valid when the paramedic is on duty, assigned to a fire department emergency response vehicle under the direction and medical control of the Milwaukee County EMS Medical Director.

- A minimum of two paramedics are required to be present at the scene to practice at the paramedic level.
- If a single paramedic is assigned to a Paramedic First Response vehicle, that paramedic may practice to the level of an EMT-Intermediate as outlined in Chapter HFS 110 of the Wisconsin Administrative Code.
- Federally controlled medications will be administered and tracked as outlined in system policies and procedures.
NOTES:

- Use the least restrictive or invasive method of restraint necessary.
- Chemical restraint may be less restrictive and more appropriate than physical restraint in some situations.
- Documentation of need for restraint must include:
  - Description of the circumstances/behavior which precipitated the use of restraint.
  - A statement indicating that patient/significant others were informed of the reasons for the restraint and that its use was for the safety of the patient/bystanders.
  - A statement that no other less restrictive measures were appropriate and/or successful.
  - The time of application of the physical restraint device.
  - The position in which the patient was restrained and transported.
  - The type of restraint used.
- Physical restraint equipment applied by EMS personnel must be padded, soft, allow for quick release, and may not interfere with necessary medical treatment.
- Spider and 9-foot straps may be used to restrain a patient in addition to the padded soft restraints.
- Restrained patients may NOT be transported in the prone position.
- EMS providers may NOT use:
  - Hard plastic ties or any restraint device which requires a key to remove.
  - Backboard or scoop stretcher to "sandwich" the patient.
  - Restraints that secure the patient's hands and feet behind the back ("hog-tie").
  - Restraints that interfere with assessment of the patient's airway.
- For physical restraint devices applied by law enforcement officers:
  - The restraints and position must provide sufficient slack in the device to allow the patient to straighten the abdomen and chest to take full tidal volume.
  - Restraint devices may not interfere with patient care.
  - An officer must be present with the patient AT ALL TIMES at the scene as well as in the patient compartment of the transport vehicle during transport.
- Side effects of midazolam may include respiratory depression, apnea, and hypotension.
TACHYCARDIA WITH PULSES

**History**
- History of arrhythmia
- History of palpitations or "racing heart"
- AICD
- History of stimulant ingestion

**Signs/Symptoms**
- Systolic blood pressure <90
- Altered LOC, dizziness
- Chest pain
- Shortness of breath
- Diaphoresis
- Palpitations
- ECG shows narrow complex > 180/min

**Working Assessment**
- Narrow complex tachycardia

NOTES:
- Contraindications to adenosine are: heart block, heart transplant, resuscitated cardiac arrest; patients taking theophylline products, Tegretol (carbamazapine, which increases the degree of heart blocks caused by adenosine) or Persantine (dipyridamole, which potentiates the affects of adenosine).
- Because of its short half-life, adenosine must be administered rapid IV bolus followed by a 10 cc normal saline flush
- After administration of adenosine, patient may have a disorganized ECG or brief period of asystole prior to conversion to sinus rhythm. Patients have reported feelings of "impending doom" during this period.
- Adenosine is not effective on atrial fibrillation.
- Carotid massage is not to be performed in the Milwaukee County EMS System.

Page 2-3
**History**
- Traumatic Injury
- Burns
- Abdominal Pain
- Sickle cell crisis
- Non-cardiac chest pain

**Signs/Symptoms**
- FACES or Verbal Pain scale rating at 4 or greater

**Working Assessment**
- Candidate for narcotic pain management

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**Notes:**
- Goal is to reduce pain scale score below 4
- IV, IM, IO routes acceptable for administration of fentanyl
- ALS transport is required for all patients receiving fentanyl
- If unable to acquire BP secondary to uncooperative patient due to painful condition, may administer fentanyl if no clinical evidence of shock AND if GCS is 14 or greater

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2-24.1
### Medical Protocol
#### Seizure

**History:**
- Reported/witnessed seizure activity
- History of seizures
- Medic alert tag
- Anti-seizure medications
- History of recent trauma
- History of diabetes
- Pregnancy
- Fever

**Signs/Symptoms:**
- Seizure activity
- Decreased mental status (post ictal)
- Sleepiness
- Incontinence
- Trauma

**Working Assessment:**
- Seizure (look for underlying cause):
  - Head trauma
  - Noncompliance
  - Fever/infection
  - Hypoglycemia
  - Overdose/poisoning
  - Alcohol withdrawal
  - Hypoxia
  - Eclampsia

**DIAGRAM:**
- Routine medical care for all patients
- Attempt to establish cause (AEIOU - TIPS - V)
  - Check blood glucose level
- Apply appropriate protocol
- Patient still seizing?
  - Yes → Attempt to establish IV
  - Midazolam 1-2 mg IV, IM, rectally (0.1 mg/kg up to 2 mg for pediatric patient)
  - Patient still seizing?
    - Yes → Contact medical control
    - No → Transport to appropriate facility
- ALS care required?
  - Yes → Attempt to establish IV
  - No → Transport to appropriate facility

**NOTE:**
- Pediatric patients with febrile seizures rarely seize more than once. If patient seizure again, evaluate for another cause.
- Status Epilepticus is defined as two or more successive seizures without a period of consciousness or recovery.
- AEIOU-TIPS-V = A - alcohol, airway, arrest; E - epilepsy, electrolytes, endocrine; I - insulin; O - overdose, oxygen depletion, opiates; U - Uremia/chronic organ failure; T - trauma, tumors, temperature; I - infection; P - psychiatric, pseudoseizures; S - Syncope, shock, stroke, sickle cell crisis; V - vascular/lack of blood flow.
# Ventricular Tachycardia with Pulses

## History

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<th>Arrhythmia</th>
<th>Signs/Symptoms</th>
<th>Working Assessment</th>
</tr>
</thead>
</table>
| AICD, MI   | Systolic blood pressure <90  
Altered LOC  
ECG shows Vtach  
Chest pain, nausea, dizziness, diaphoresis, palpitations | Unstable Vtach with pulses |

## History

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<tr>
<th>Arrhythmia</th>
<th>Signs/Symptoms</th>
<th>Working Assessment</th>
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</table>
| AICD, MI   | Systolic blood pressure >90  
LOC normal  
ECG shows Vtach  
May or may not have chest pain, nausea, dizziness, diaphoresis, palpitations | “Stable” Vtach with pulses |

## Working Assessment Diagram

1. **ECG shows Vtach; patient has pulse**
2. **Pt > 16 years old?**
   - Yes: **Unresponsive and systolic BP <90?**
     - No: **Synchronize cardiovert= 100 joules**
     - Yes: **Patient converted?**
       - Yes: **Patient converted?**
         - Yes: **Contact medical control**
         - No: **Synchronize cardiovert= 150 joules**
       - No: **Defibrillate= 300 joules**
       - Yes: **Patient converted?**
         - Yes: **Patient converted?**
           - Yes: **Contact medical control; consider 2 mg midazolam IV, IM, prior to possible cardioversion**
           - No: **Monitor and transport to appropriate facility**
         - No: **Amiodarone 150 mg IV/IO (add to 100 cc D5W and run over 10 minutes)**
            - Yes: **Patient converted?**
              - Yes: **Contact medical control; consider 2 mg midazolam IV, IM, prior to possible cardioversion**
              - No: **Monitor and transport to appropriate facility**

## Notes:
- Adenosine 12 mg may be ordered for the patient with a wide complex tachycardia that does not respond to amiodarone.
- Defibrillation/synchronization may need prior sedation and may be ordered as the first intervention in the unstable patient.
POLICY: Management of controlled substances within the Milwaukee County EMS system is a collaborative effort of several system stakeholders to ensure compliance with system and federal standards.

Place controlled substance order with Froedtert Pharmacy
Pick up drugs and paperwork from pharmacy
Verify accuracy of order and paperwork
Package drugs in tamper evident envelope
Log administration record on controlled substance tracking sheet
Deliver drugs and paperwork to FD
Obtain appropriate signatures on FD & EMS copies of administration record
File EMS copy of administration record
Document daily count, visual and expiration date check on daily check sheet

If any discrepancies?

Yes

Any discrepancies?

No

Report out of balance or damaged vials
Return remaining vials and paperwork to EMS
Investigate discrepancies
Report lost or stolen vials

Expired drugs?

Yes

Contact EMS with drug and control # information; make arrangements to return expired drugs and corresponding paperwork

No

Return completed administration record to EMS

Log return of administration record on controlled substance tracking sheet
Copy completed administration record and forward copy to QA
Return completed original administration record to pharmacy

Return completed daily check sheet to QA
Audit administration record documentation for accuracy and completion
Audit daily check sheets for accuracy and completion

Complete random in-field audits
Document and file all audit results

4-2.2
POLICY: Controlled substances will be ordered when the paramedic unit stock is down to minimal allowance, upon receipt of the completed controlled substance tracking sheet.

Receive completed original copy of controlled substance sheet OR vials of expired drug along with sheet accounting for vials administered

Photocopy the original form and file it with the blank, signed form in the controlled substance file

Return original, completed form to the pharmacy, along with the order for more controlled substances

Pick up order from FMLH pharmacy upon notification that order is ready

Verify that all medications ordered have been received

Refer to Controlled Substance Distribution Policy
POLICY:  A paramedic unit may place an unscheduled “emergency” supply order if the unit is dangerously low on or out of a necessary commodity.

Receive "emergency" supply order

Order involves medications?

Yes
Fill out medication order

Controlled substance?

Yes
Call Froedtert Pharmacy Controlled Substance Tech to place order

No
Fax order to pharmacy

Supplies from FMLH?

Yes
Forward supply order to FMLH

No
Obtain supplies from MC EMS Store Room

No Supplies from FMLH?

Yes
Receive notification that order is ready for pickup

Notify MED unit that supply order is ready for pickup at FMLH

No
Notify MED unit that controlled substances are ready for pick up at MC EMS offices

NOTES:
- Unscheduled orders must be placed during regular office hours.
- Contact the Informatics Manager for emergent orders.
POLICY: Controlled substances will be distributed and accounted for in accordance with state and federal standards.

Report to FMLH pharmacy upon notification that order is ready

Pharmacy and Stores Clerks place controlled substances in and seal tamper evident envelope and enter date issued on controlled substance administration record

Write REF # (control #) from controlled substance sheet on the tamper evident envelope

Photocopy blank controlled substance administration record, creating copies for FD and MC EMS

Verify that all medications ordered have been received

Print 5 labels with the REF# (control #) from the controlled substance administration record

Attach envelope to controlled substance administration record with address label for return to MC EMS Stores Clerk

Deliver the tamper evident envelope, 5 stickers, the administration record and envelope to the fire station

Remove identity tag from tamper evident envelope and affix to or write number on controlled substance administration record; verify numbers are correct

Delivery to North Shore?

Yes

Turn tamper evident envelope, REF # (control #) stickers, original blank controlled substance administration record and the addressed envelope over to FD personnel authorized to accept controlled substances

Obtain signature of FD personnel taking receipt of the drugs on FD and EMS copies of the controlled substance administration record

Place controlled substances and corresponding FD documentation in the administrative safe

No

 Obtain signature of FD staff personnel taking receipt of the drugs on FD and EMS copies of the controlled substance administration record

File the signed EMS copy of the controlled substance administration record in the controlled substance file
POLICY: Administration of controlled substances will be uniformly documented to accurately reflect usage and waste. Controlled substances will be visually inspected for seal damage and volume discrepancies.

NOTES:
- MC EMS will perform routine visual checks as well as auditing each MED unit to assure documentation is complete and accurate.
- Records will also be reconciled with the FMLH pharmacy at the end of the year.
POLICY: Ambulances, kits, equipment will be routinely checked to ensure they are in good working order, completely stocked and clean. Complete patient care documentation includes all information necessary for continuing patient care, billing and electronic data collected by the monitor/defibrillator. All clocks used in the course of patient care (dispatch, monitor, personal wristwatch, EPC, etc.) shall be synchronized to the National Institute of Standards and Technology (NIST) time on a daily basis.

For every patient encounter:
- Complete the patient care record and distribute as directed for continuing patient care, billing, and data collection.

On a daily basis:
- Check and restock all kits and supplies at the beginning of the shift and after every run.
- Ensure that all equipment is in good working order at the beginning of the shift and after every run.
- Maintain the vehicle and equipment in a clean and orderly fashion.
- Return any defective item to the appropriate department for replacement or repair (refer to Equipment Exchange Policy.)
- Count and perform visual inspection of controlled substances; justify with control sheets. Any discrepancy is to be accounted for before the previous shift is relieved. Inability to account for a controlled substance or irregularity in appearance of a medication vial is to be reported immediately to Department Administration.
- Rotate the batteries in the monitor/defibrillator.
- Check Rosetta battery and replace as needed.
- Document that the monitor/defibrillator was checked for:
  - Paper quantity and feed
  - Operations of all controls
  - Operation of defibrillator
  - Non-invasive blood pressure monitor, where applicable
  - Date and time synchronization to NIST time.
- Perform a user test on the monitor/defibrillator and file the test results in the appropriate location.
- Check ETCO2 cable integrity
- Rotate portable radio batteries.
  - Place fully charged battery in the radio.
  - Charge the used battery until the cycle is complete; remove from charger and store.
- Forward EMS run reports to Fire Dept. Administrative offices, who will prep for weekly pick-up by Milwaukee County EMS.
- Upload all patient care information from monitor/defibrillator to the station computer; clear the data card.
- Ensure station computer for uploading ECG monitoring information has the correct date and is synchronized to the atomic clock

On a weekly basis:
- In addition to cleaning the patient area after each run, on the day specified by the fire department, wash the interior of the vehicle, stretcher, stair chair and backboards with phenolic or quaternary compound solution following label directions.
- Clean the exterior and interior vehicle compartments.
- Test the voice and telemetry radio equipment on the assigned day via mobile and portable telemetry radios. Test portable and mobile trunking radios.
- Rotate medications such that waste due to expiration does not occur.

On a biweekly basis:
- On the day determined by the fire department, inventory all supplies and check expiration dates. Prepare a list of needed items.
- Complete the supply order form and e-mail to the Milwaukee County EMS offices before Friday prior to delivery date.

On a monthly basis:
- On the day specified by the fire department, remove all contents of the kits. Check the expiration dates on all medications and fluids. Return expired medications to the Milwaukee County EMS Stores Clerk. Wash out the kits with phenolic or quaternary ammonium compound solution following directions. Dry completely before replacing contents.
- On the day specified by the fire department, remove all medications and fluids from vehicle stock, checking expiration dates. Return expired medications to the Milwaukee County EMS Stores Clerk. Expired controlled substances must be returned with corresponding paperwork immediately. Wipe out compartments with phenolic or quaternary ammonium compound solution following directions. Dry completely before replacing contents.
- As scheduled, discharge and recharge all monitor/defibrillator batteries as per manufacturer operational instructions listed in the manufacturer's manual. Any battery with levels of less than 70% displayed after 3 discharge-charge cycles should be brought to the EMS Supervisor for replacement. Note the battery results on the back of each battery.
Milwaukee County EMS
Daily Controlled Substance Count and Defib Check Sheet

Note: Signing your name and documenting your paramedic number indicate you attest to the accuracy of and the controlled substance count, have visually inspected the vials for tampering, and have completed the daily defibrillator test.

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<th>Month</th>
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 Milwaukee County EMS  
Daily Controlled Substance Count and Defib Check Sheet  

Note: Signing your name and documenting your paramedic number indicate you attest to the accuracy of and the controlled substance count, have visually inspected the vials for tampering, and have completed the daily defibrillator test.

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<th>Date</th>
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**CONTROLLED SUBSTANCE ADMINISTRATION RECORD**

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<th>VIAL</th>
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<th>Patient Name</th>
<th>Report #</th>
<th>Paramedic #1</th>
<th>ID #</th>
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<th>ID #</th>
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**Drug:** FENTANYL 100 mcg CARPUJECT  
**Qty:** 5  
**Date issued by pharmacy:**  
**Control #:**  
**Expiration date:**  
**MED Unit:**  
**Received by (print name):**  
**Signature:**  
**Title:**  
**Date delivered:**  
**Sealed envelope #:**

*Signature Required*

_Froedtert Memorial_  
_Controlled Substance Administration Record_
**CONTROLLED SUBSTANCE ADMINISTRATION RECORD**

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Date issued by pharmacy: ______________________________________

Control #: ______________________________________

Expiration date: ______________________________________

MED Unit: __________________________

Received by (print name): __________________________

Signature: __________________________

Title: __________________________

Date delivered: __________________________

Sealed envelope #: __________________________
SUBSTANCE DOCUMENTATION AUDITING

POLICY: Each MED unit will be audited to assure documentation of controlled substance administration accurately reflects usage. Records will also be reconciled with the FMLH pharmacy at the end of the year.

1. Retrieve completed controlled substance administration record from file
2. Identify MED Unit, date, patient name and patient care record number for each vial on the administration record to be audited
3. Look up corresponding patient care record
4. Verify Control # on patient care record matches the Control # on the controlled substance administration record
5. Verify documented amount given matches the amount documented on the patient care record
6. Verify signatures match the paramedics’ names on the patient care record

Documentation on administration and patient care records match?
- Yes: Note documentation was found to be in order on audit sheet; date and sign sheet
- No: Forward discrepancies to the Quality Manager for further investigation

File audit results

NOTES:
- Each MED unit will be audited at least twice per year for each controlled substance carried.
POLICY: Milwaukee County EMS will perform random field audits of controlled substances and documentation.

- Determine unit(s) to be audited
- Complete a drug count to ensure accuracy of daily documentation
- Complete visual exam to ensure accuracy of daily documentation
- Notify FD administration of situation
- Confiscate the entire 5-pack of drugs in question and corresponding paperwork
- Return drugs and corresponding paperwork to Milwaukee County EMS for further investigation
- Order replacement drugs as necessary
- Log incident in Controlled Substance Incident Log
- File reports with DEA or legal authority as necessary
- Log the MED unit, date, and completion of the audit
- Highlight the most recent complete line on the administration record; write the date and initial the highlighted line
- Request FD to fax copy of corrected administration records to MCEMS when discrepancy is resolved
- Confirm correction
- Review controlled substance administration records for accuracy and completion
- Any discrepancy?
  - Yes
  - Notify FD administration of situation with instructions to rectify discrepancy ASAP
  - No
- Any discrepancy?
  - Yes
  - No

Page 1 of
POLICY: Fire departments will forward the completed Daily Controlled Substance Count and Defib Check Sheets to the Milwaukee County EMS Quality Section on a monthly basis.

The MC EMS Quality Section will audit the forms for accuracy and completion. The results of the audit will be filed with the sheets.

```
Retrieve Controlled Substance Daily Check Sheet

Log MED unit, month and year on audit spreadsheet

Review sheet to ensure all counts are in balance as recorded

Review sheet to ensure all required signatures are recorded

Any discrepancies? No → Sign and file audit findings with daily check sheets

Yes

Note discrepancies on audit form

Initiate investigation to determine where discrepancy occurred

Document findings and action taken to address discrepancy
```
DOCUMENTATION MONITORING

POLICY: Controlled substances will be monitored on a continual basis to ensure documentation, accounting, and reporting are complete and accurate.

Receive completed Controlled Substance Administration Record from FD

Review for completion and accuracy upon receipt

Any discrepancies? Yes→ Forward to QA Specialist

No

Log return of administration record on Controlled Substance Tracking Sheet

Copy original completed Controlled Substance Administration Record

Forward original to Froedtert Pharmacy and copy to Quality Assurance Specialist

NOTES:

- Alert the FD EMS Liaison if a Controlled Substance Administration Records is not returned in a timely manner or if discrepancies in the documentation are found.
Milwaukee County EMS Controlled Substance Tracking

MED UNIT: _____________

<table>
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<tr>
<th>Distribution Date</th>
<th>Control Number</th>
<th>Midazolam</th>
<th>Fentanyl</th>
<th>Date Sheet Returned</th>
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POLICY: Milwaukee County EMS Quality Management Section will conduct infield physical audits, as well as documentation audits as established by system policy.

Results of audits performed will be documented and retained for a minimum of five (5) years.

Audit results are confidential and are protected by Wisconsin statutes.
**POLICY:** Milwaukee County EMS is responsible for maintaining accountability and will document any and all discrepancies in tracking controlled substances.

1. Fire department identifies out-of-balance controlled substance
2. Conduct internal search in attempt to locate missing drug
3. Missing drug found?
   - NO: Notify EMS Supervisor, Program Director, and Medical Director immediately of discrepancy
   - YES: Remove remaining vials and corresponding control sheet from drug box
      - Complete Controlled Substance Out-Of-Balance Form and forward with remaining vials and control sheet to MC EMS offices
      - Begin collection of written documentation including:
        - Who noticed drug missing, when it was noticed missing; when last count balanced; results of interviews of all staff working since last balanced count
        - Complete a conclusion report with process and findings of the investigation; remediation plan including how to prevent future occurrences
        - Forward copies of all documentation to MC EMS offices

4. Missing more than 1 dose from 1 incident?
   - NO: Notify appropriate law enforcement agency and follow additional instructions provided
   - YES: MC EMS will attach a copy of the Out-Of-Balance report to the controlled substance tracking sheet and forward to the pharmacy
      - Forward a copy of the documentation to the Quality Manager for incident logging purposes
      - All documentation will be filed by the Stores Clerk in the Controlled Substance Tracking File

**NOTE:**
- The Medical Director or Program Director may request reporting to the appropriate law enforcement agency.

4-13.1
MILWAUKEE COUNTY EMS
CONTROLLED SUBSTANCE OUT-OF BALANCE REPORT

I. Out-of-balance controlled substance (check one)
   ☐ Fentanyl 100mcg/2mL   ☐ Midazolam 5 mg/5mL   Control #

II. Out-of-balance discovered by MED Unit _________ Date __________________________
    Paramedic signature ___________________________ Paramedic # _________
    Paramedic signature ___________________________ Paramedic # _________

III. Investigation:
    A. Step 1: Confirm accuracy of controlled substance tracking sheet
       ☐
    B. List patient names receiving this drug and compare accuracy to tracking sheet
       1. ___________________________________________ ☐
       2. ___________________________________________ ☐
       3. ___________________________________________ ☐
       4. ___________________________________________ ☐
       5. ___________________________________________ ☐
    C. If out-of-balance still not corrected, list all paramedics working on this unit since the last correct drug count:
       1. ___________________________  Paramedic # _________
       2. ___________________________  Paramedic # _________
       3. ___________________________  Paramedic # _________
       4. ___________________________  Paramedic # _________
    D. Submit this form immediately upon completion to MC EMS offices

IV. Follow-up (to be completed by Fire Department Administration)

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

FD Administration Signature ___________________________ Date __________
Policy: A Drug Enforcement Administration (DEA) Form 106 will be completed in the event of confirmed lost or stolen controlled substances within the Milwaukee County EMS system.

A copy of the report will be printed and kept on file by the Quality Manager for a minimum of 2 years as required by the DEA.
**Policy:** MED units will check controlled substances daily for seal damage and volume discrepancies. Any discrepancy will be reported to Fire Department Administration, who in turn, will report the discrepancy to MC EMS.

- Receive report of discrepancy
- Request fire department investigation of possible reason for discrepancy
- Request tracking sheet and remaining vials to be sealed and delivered to MC EMS ASAP
- Examine vials to verify discrepancy
- Photograph the vials; label and save photographs to the Controlled Substance Incident Log on the Incident Log computer drive
- Log in the Controlled Substance Incident Log
- Review Controlled Substance Incident Log for an incident for the same MED unit within the past six months
  - Other reason to warrant vial testing? No
  - Place vials and tracking sheet in tamper evident, sealed envelope
    - Label envelope with date and MED Unit
    - Store envelope in EMS Safe for one year or until recalled by Froedtert Pharmacy
    - After one year or recall, return vials and tracking sheet to Froedtert Pharmacy
  - Any incidents within past 6 months? Yes
    - Send vial(s) for testing
      - Test positive for diversion?
        - Yes
          - Report diversion to DEA
          - Report loss/theft to Fire Administration
          - Proceed as directed by DEA/Fire/EMS Administration
        - No
          - Send vial(s) for testing
      - No
POLICY: Controlled substances issued in the previous year are recalled in the second quarter of the following year to complete Froedtert Pharmacy’s annual account of the controlled substances issued and used. The pharmacy will replace the drugs and tracking sheets.

Stores Clerk receives pharmacy’s list of all outstanding controlled substances issued in the previous year

Stores Clerk notifies all MED units with outstanding drugs to return the drugs and tracking sheets to the pharmacy

MED units turn in the old drugs and tracking sheets to the pharmacy; receive new drugs with corresponding tracking sheets

MED units immediately take the new drugs and tracking sheets to MC EMS, where Stores Clerk will log the drugs, copy the tracking sheet and issue the vial stickers

MED units return to service
POLICY: Controlled substance expiration dates will be monitored to prevent unnecessary disposal of expired drugs.

1. Prepare controlled substance for distribution

2. Document expiration date on Controlled Substance Administration Record

3. Enter control number and expiration date in Controlled Substance Monitoring (CSM) database prior to distribution

4. Distribute controlled substances per protocol, obtaining required signatures upon delivery

5. CSM displays expiration warning?
   - Yes: Order replacement drugs from Froedtert pharmacy
   - No: Continue routine monitoring of expiration dates

6. Contact MED Unit; arrange to deliver new medications and pick up drugs with corresponding administration records

7. Return drugs and paperwork to Froedtert pharmacy