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:

CATEGORY	INTERPRETATION
CI	**High potential for abuse.** No medical value
CII	**High potential for abuse.** Use may lead to severe physical or psychological dependence.
CIII	**Potential for abuse less than CI and CII.** Use may lead to low to moderate physical dependence or high psychological dependence.
CIV	**Low potential for abuse relative to CIII.** Use may lead to limited physical or psychological dependence.
CV	**Low potential for abuse relative to CIV.** Use may lead to limited physical or psychological dependence, less than CIV.

Possible controlled substances for use by ambulance providers:

CII Morphine, Fentanyl, Hydropmorphone
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.DEAdiversion.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) 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.
   c) Expired inventory should be stored and accounted for in the same manner as all other controlled substances.

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.