West Virginia Office of Emergency Medical Services
Controlled Substance Policy Statement

This policy establishes the standard for the management of Controlled Substances by WV EMS agencies in accordance with Federal DEA Rules and Regulations, WV Legislative Rule §64CSR48-4.12 and WV Legislative Rule §64CSR48-6.2.h. The Federal Rule is found in the Code of Federal Regulations (Title 21 CFR, Part 1300-1399) and the Controlled Substance Act. The possession and administration of controlled substances is governed by the U.S. Department of Justice Drug Enforcement Administration. This can be accessed via the DEA website.

www.deadiversion.usdoj.gov

Definition of Controlled Substance Schedules

Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. An updated and complete list of the schedules is published annually in **Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15**. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused. Some examples of the drugs in each schedule are listed below.

Schedule I Controlled Substances

Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.

Some examples of substances listed in Schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

Schedule II Controlled Substances

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, and codeine.

Examples of Schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics include: combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®), products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®).

Examples of Schedule III non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and ezogabine.

DEA Registration.

The EMS Agency may obtain DEA registration by one of three methods.

- The Agency Medical Director may apply as the "Registrant", thereby obtaining a registration number (DEA Number) specific to the Agency. This "registration" would be separate from any other DEA registration the Agency Medical Director may have. Agency medications would be obtained utilizing this registration number.
- The Agency may apply as a "Registrant "in the role of a Mid-Level Provider. The Agency would have its own DEA Number and medications would be obtained through that registration number.
- The Agency may obtain controlled substances through the Hospital Registration Number if the ambulance service is operated by the hospital.

DEA considers each permanent station, a storage area. Therefore each address where controlled substances are stored must have a valid DEA Registration number. Subsequently each station needs to have a separate DEA registration number.

Ordering controlled substances:

**REFERENCE Federal Rule Title 21 CFR Section 1305.06 / Section 1305.11

All controlled substances must be ordered utilizing **DEA FORM 222**. This form can be obtained from the DEA and must be completed accurately.

Inventory:

**REFERENCE Federal Rule Title 21 CFR Section 1304.11 Inventory Requirements

There will always be an inventory of controlled substances within the system. This inventory is the direct responsibility of the Registrant.

Records for Schedule II Controlled Substances must be maintained separately from all other records and be immediately available for inspection. If the records are maintained on a computer inventory system, this record must be immediately available in printed format. Records for Schedules III-V do not need to be separate, but they must be retrievable in a reasonable time frame.

Inventory reconciliation must be performed every two (2) years. A complete written 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, and name of controlled substance, amount administered, and the printed name of the person administering the controlled substance and a witness. DEA requires Controlled Substance Records to be maintained for (2) years.

Out-of-Service

Ambulances that are out-of-service (inoperable, not available for current operation, no crew available, not functional) shall have their controlled substances removed, secured and accounted for according to the licensed EMS Agency medication management plan. This does not apply to an ambulance that is "out of service" secondary to the crew having lunch, completing reports or other duties, which prevent temporary response to calls.

Carry bags / Jump Bags

No "CARRY BAGS /JUMP BAGS" (bags carried by personnel in their personal vehicle) containing controlled substances shall be permitted. No controlled substances can be stored in personal vehicles or on personal property.

Storage

** REFERENCE http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section3

Only controlled substance approved by the WV Office of EMS shall be carried on ambulances.

Controlled substances, not on an ambulance, should be stored in a secure fashion in a double locked tamper resistant cabinet. Controlled substances shall be stored with the ability to examine for tampering, expiration dates, and inventory counts. When the storage cabinet is accessed, the inventory should be examined for tampering, and inventory counts shall be reconciled.

Access

In order to minimize the possibility of diversion, the registrant must limit access to the storage areas for controlled substances to a minimum number of authorized employees.
All access shall occur in the presence of two personnel.
Controlled substances shall be accessed by ALS providers or Registrants designated personnel.
All access should be recorded and witnessed.
The Registrant may designate other individuals to access controlled substances but the designation must be in writing identifying the individuals granted access. Refer to **Title 21 Code of Federal Regulations (C.F.R.) §§ 1305.05** for further information on Power of Attorney.
Only ALS providers can pick up and transport controlled substances (incidental contact by Rapid Responders or other ambulance personnel helping the ALS provider carry equipment while on scene is allowed) but the ALS provider must be in control of access to these medications at all times.
ALS providers may have medication stored in the ambulance "jump bag". However the "jump bag" must be secured using a device such as a tamper detectable plastic lock. The bag must be stored in a secured locked location on the ambulance or in the Agency Station. ALS providers or the Registrants designated personnel (Power of Attorney as described above) must be in control of the bag at all times when not locked in a secure location.

Documentation

** REFERENCE http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section4
Every Agency must maintain a log of controlled substances.
Every use of controlled substance shall be documented in the patient care record and signed by 2 providers.
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
All documentation shall have a minimum of one printed name in electronic or hand written format.
All Controlled Substance documents shall be securely stored for a minimum of two (2) years, (§64.48.4.13.).

Daily accountability

At the start of every shift or transition of crew members, all controlled substances stored on the ambulance shall be examined for evidence of tampering, expiration dates, and count. Counts shall be verified against the last count. Any discrepancy or evidence of tampering shall be reported immediately to agency Supervisor and Medical Director and law enforcement and WV OEMS.

Theft or loss of a controlled substance needs to be reported to the DEA within 1 business day utilizing DEA Form 106. Any discrepancy shall be reported to WV OEMS in writing and local or state law enforcement.

Facility Replacement

Controlled substance should be replaced according to the licensed EMS agency medication management plan, (§64.48.4.12.) This also applies to replacement of expired medications.

After receiving replacement inventory, the following should be verified by two people:

- Medication
- Amount
- Date received
- Current count
- Inspection of the entire replacement inventory for tampering and expiration dates

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.

Wasting:

Any amount of a controlled substance that is wasted should be witnessed by at least two people and recorded. Any excess medication remaining, after administration to patient, should be wasted under supervision by a nurse at the receiving facility. The name of the nurse witnessing the wastage must be documented in the run sheet. If nursing staff unwilling to witness wastage, the other crew member (s) may witness and sign the run sheet. DEA prefers to utilize a 3rd party witness when possible.

Theft or Loss of Controlled Substances:

** REFERENCE http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index

Federal regulations require that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in their area, **DEA Form 106**, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss. (21 C.F.R. § 1301.76(b)). Any theft or loss shall be reported to WV OEMS in addition to the DEA, in writing within one business day.

DEA controlled substance 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. Submission to WV OEMS shall be completed in writing with email meeting that requirement.

If a registrant does not have internet access, a paper copy of the DEA-106 form can be requested by writing to:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrissette Drive
Springfield, VA 22152

Breakage and Spillage:

** REFERENCE http://www.deadiversion.usdoj.gov/faq/general

Breakage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, spillage, or some other form of destruction, any ***recoverable*** controlled substances must be disposed of according to DEA requirements. Damaged goods may be disposed of through shipment to a "reverse distributor" or by a DEA approved process. The DEA recommends that any registrant seeking to dispose of controlled substances first contact the nearest DEA Diversion Field Office for disposal instructions. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA.

If the breakage or spillage is ***not*** recoverable, the registrant must document the circumstances of the breakage in the inventory records. Two individuals who witnessed the breakage must sign the inventory records indicating what they witnessed. The submission of a DEA Form 41, *Registrants Inventory of Drugs Surrendered,* is not required for non-recoverable controlled substances.

The DEA procedures established for the destruction of controlled substances shall not be construed as altering in any way the state laws or regulations for the disposal of controlled substances. When this disposal occurs, it must be reported to the DEA on a DEA Form 41.

Disposal / Expired Drugs:

** REFERENCE http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index

http://www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_21

(Title 21 CFR Section 1307.21) Controlled substances that are expired or need to be removed from inventory for any reason cannot be wasted. The Registrant will 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 approval from the DEA District Office.

Call the Charleston DEA Office (304) 347-5209 for a list of active reverse distributors.

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