





Controlled Substance Policy

CHAPTER:	2000	Number:	2050	REVIEWED:	6/6/2023
REPLACES:	3/20/2013,6/14/2017		ENACTED: 3/20/2013		
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APPROVED:			Joe Hoffman, Medical Program Director		
APPROVED:	 <small>Jeff Faucett (Jun 7, 2023 13:26 PDT)</small>		Jeff Faucett, Chair		

I. Purpose

To establish policies and procedures for Kitsap County EMS agencies pertaining to the acquisition, administration, and security of controlled substances in compliance with Federal Controlled Substance Acts and State rules.

II. Policy:

All agencies will comply with the Controlled Substances Act of 1970 as well as State and Federal laws or rules regarding controlled substances. Each EMS agency will develop and comply with an agency-specific Controlled Substance plan approved by the Kitsap County MPD.

All agencies must keep current Controlled Substance Plans on file at the Kitsap County EMS Office.

III. Procedures:

A. DEA Registration

1. One or more persons at each Agency must have a power of attorney agreement with MPD allowing them to sign the DEA form 222.
2. Each Agency will be responsible for securing and maintaining the required registration with the DEA. This procedure will be completed in conjunction with the MPD through the EMS office in compliance with applicable laws. A copy of the agency certificate will be provided to the EMS office for record-keeping purposes.

B. Record Keeping



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1. All record-keeping related to controlled substances shall be maintained per the "Protecting Patient Access to Emergency Medications Act of 2017" subsections (a) and (b) of section 307 for all controlled substances that are received, administered, or otherwise disposed of pursuant to the Agency's registration, without regard to subsection 307(c)(1)(B). Such records 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, for a minimum of three years. Upon request, these records will be made available to the MPD and appropriate State, Federal, and local law enforcement agencies; all of whom will be held responsible for maintaining the confidentiality of the information contained therein.
2. Use and storage records for schedule II medications must be kept separate from the schedule III-V medication records.
3. In addition to daily inventory, a formal, complete inventory of controlled medications on hand must be done at least once every two years. A complete and accurate written, typewritten, or printed record must document controlled medications on hand. Per DEA regulations, this audit must be kept for two (2) years. The audit should specify that it is the bi-annual audit, the date, and the audit results. The audit shall be kept in a secure area and available at all times.
4. Use and storage records for schedule II medications must be kept separate from the schedule III-V medication records.
5. All record-keeping related to controlled substances shall be maintained in accordance with the "Protecting Patient Access to Emergency Medications Act of 2017" subsections (a) and (b) of section 307 for all controlled substances that are received, administered, or otherwise disposed of pursuant to the Agency's registration, without regard to subsection 307(c)(1)(B). Such records 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 for a minimum of three years. Upon request, these records will be made available to the MPD and appropriate State, Federal, and local law enforcement agencies; all of whom will be held responsible for maintaining the confidentiality of the information contained therein.



C. Inventory

1. Each Agency will establish a par level for reserve stock and the amount of each controlled medication stored in each ALS unit. This will be dictated by past use, patient volume, and turnover of expired medications.
2. Each Agency will stock at least the minimum of the following controlled substances on each registered ALS unit:

Medication	Concentration, Size	Minimum Quantity
Fentanyl Injection	100mcg/2 mL	2
Valium (Diazepam®)	10mg/2mL	2
Midazolam (Versed®)	5mg/5mL, 5mg/1mL	2
Morphine Injection	10mg/mL, 1 mL	2
Ativan (Lorazepam)	5mg/mL, 2mL	2
Ketamine	50mg/mL, 10 mL	2

3. From the Kitsap County EMS formulary, each Agency can choose two (2) opiate analgesics, two (2) benzodiazepines, and Ketamine.
4. The agency representative will maintain inventory according to the Agency specific Controlled Substance Plan.
5. Prescription forms may not be used to order controlled medications for storage or used by an EMS agency.
6. Each Agency authorized to carry nitrous oxide will stock a maximum of two bottles per registered ALS unit.

D. Ordering

1. Each Agency will establish a business relationship with a DEA, and State authorized pharmaceutical distributor.
3. All controlled substances will be ordered and shipped according to the Agency specific plan and DEA and State regulations.

E. Storage



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1. All controlled substances will be stored in a substantially constructed locking cabinet within the confines of the ALS unit or the central business.
 - a. First-out medications will be secured with inventory control locks.
 - b. Access should be limited to the paramedic assigned to the unit, those under his/her supervision, the operations supervisor, or his/her designee.
2. All medications will be stored in accordance with the manufacturer's recommendation and in compliance with Federal and State laws.

F. Security

1. Authorized Staff must perform daily verification and inspection of all controlled substances at the beginning of each shift. Medication counts shall be recorded on verification logs.
2. In the event of an unaccounted discrepancy, a Medical Officer or agency equivalent must be immediately notified.
 - a. The off-going paramedic will remain on premises until a Controlled Medication Replacement Form and an Incident Report are completed and provided to the Medical Officer or Agency equivalent. A copy of the Incident Report will be provided to the EMS office by the next business day.
 - b. In the event of theft, loss, diversion or tampering of controlled substances, the Agency will, within one (1) business day, notify the DEA and local law enforcement by FAX or email. A completed DEA Form-106 "Report of theft or loss" must be completed within 30 days and sent to the DEA and the Kitsap County MPD. The MPD will send a copy of Form -106 to the Washington State Board of Pharmacy and other applicable agencies as required.
 - c. Medication that appears to have been tampered with must be secured for DEA investigation. Report theft, loss, diversion or tampering to the Seattle DEA office:

DEA Office of Diversions Control
400 S 2nd Avenue West
Seattle, WA 98119

G. Administration/ Waste/ Documentation of Controlled Substances



1. Administration of controlled substances will be governed by the Kitsap County EMS & TCC Patient Care Protocols and online physician orders.
2. Any medication remaining after pre-hospital therapy is terminated must be wasted. The waste must be witnessed and documented on the MIR by an EMT, another Paramedic, RN, ARNP, PA, or a Physician.
3. Documentation of controlled substance usage on the MIR will comply with EMS policy and include the following additional information:
 - a. date;
 - b. patient name;
 - c. signature of administering paramedic;
 - d. name of ordering physician;
 - e. name and strength of medication;
 - f. amount administered;
 - g. amount destroyed;
 - h. signature of destroyer and witness; and
 - i. receiving hospital.
4. In the event of breakage or other contamination of a medication, making it unusable, the paramedic will submit a Controlled Medication Replacement Form to their immediate supervisor. The supervisor will then notify the Medical Officer or Agency equivalent, which is responsible for informing and forwarding the Form to the EMS office by the next business day.
5. In the event that the medication is opened but not used, the paramedic shall waste the medication according to procedure in the presence of a documented witness. A copy of the Unusual Incident Report will be sent to the EMS office.

H. Replacement of controlled medication

1. The authorized agency representative shall replace controlled medications through their registered distributor in accordance with the agency "Controlled Substance Plan" on file at the EMS Office.
2. Disposal of expired controlled medications will be accomplished by each individual Agency.



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3. This requirement does not include medications wasted after a single patient's use. Agent or agency records must be kept for two years. Patient care records and agency-controlled medications logs, document proof of use or disposal.
4. Disposal of expired controlled medications can occur by one of the following options:
 - a. Outdated or unusable schedule II-V medications must be disposed of by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." See appendix A-3 for a complete list of Reverse Distributors. Schedule II controlled substances should be transferred via the DEA form 222. Schedule III-V compounds may be transferred via invoice. The agency representative should maintain copies of the records documenting the transfer and disposal of controlled substances for two years.
 - b. Outdated or unusable schedule II-V medications can be disposed of with secured medication disposal offered through public health or law enforcement. A separate memorandum of understanding must be in place between the agencies involved. Schedule II controlled substances should be transferred via the DEA form 222. Schedule III-V compounds may be transferred via invoice. The agency representative should maintain copies of the records documenting the transfer and disposal of controlled substances for two years.
 - c. Outdated or unusable schedule II-V medications can be disposed of using an inert material offered by a private vendor. A record of disposed of Schedule II-IV substances will be generated by the agency representative and witnessed by another paramedic. The container will be disposed of as the private vendor recommends or in solid waste. The agency representative should maintain copies of the records documenting the transfer and disposal of controlled substances for two years.

I. Quality Assurance/ Compliance

1. The MPD, or his/her designee, will review the MIRs periodically for appropriate usage and documentation of controlled medication administration.
2. The MPD, or his/her designee, will review the controlled medication verification logs periodically.



References

Form DEA-106, Report of Theft or Loss of Controlled Substances - Revised October 2008

<https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp>

DISPOSAL OF CONTROLLED SUBSTANCES

Section 1307.21 Procedure for disposing of controlled substances

Attachments

Unusual Incident Report

Approved


2050 Controlled Substance Policy. Approved 6.6.2023

Final Audit Report

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