Controlled Substance Handling and Storage

PURPOSE:
The purpose of this policy is to define the storage and handling procedures for controlled substances used by the patrol. Controlled substances such as fentanyl (schedule II), versed, and ketamine (schedule III) are very useful for treating pain and other acute problems such as seizures. They are also governed by federal regulations because they are medications which are at high risk for abuse, theft, and diversion. The secure and diligent storage of these medications is critical to preserve the patrol's access to these medications and prevent criminal and civil penalties for Mt Bachelor or its employees.

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1. PERSONELL:

A. Screening

Only staff who 1) have undergone a background check as part of their hiring process with Mt Bachelor or for certification through state EMS agencies; 2) have completed attestation paperwork; and 3) have been approved by the medical director may access medications, carry them on their person, or complete stocking, inventory, or wasting procedures.

B. Exclusions

No employee with a felony conviction for controlled substance offenses, or who has had a DEA registration denied, revoked, or surrendered for cause, may be given access to controlled substances.

C. Recording

The patrol medical lead or their designated substitute must maintain a list authorized individual approved by the medical director to access controlled substances.

D. Revocation

Any approved employee who is found to have violated the policies and procedures for controlled substance handling and storage may have their approval revoked for such violation. The medical director may also revoke the access of any approved employee at any time at the director's discretion.

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2. ACQUISITION:

A. Authorized Purchasing

Only the DEA-registered medical director (or authorized agent with Power of Attorney) may order Schedule II–V medications. Fentanyl is a Schedule II substance that requires DEA Form 222 (or electronic CSOS) for each order. Midazolam (Schedule IV) and ketamine (Schedule III) are ordered through standard purchase orders or invoices from a licensed supplier (no Form 222 required for III–V).

B. Verified Suppliers

Purchases must be made from DEA-registered suppliers (wholesalers or pharmacies) holding valid DEA and Oregon licenses. If using a new supplier, the ordering party should first verify the supplier's registration and license status.

supplier information. Only persons granted Power of Attorney by the DEA registrant may execute Form 222. Maintain executed Forms 222 in a dedicated file (separate from other records) and keep copies of supplier receipts attached. The supplier will ship the Schedule II only to the clinic's registered address after verifying the form.

D. Orders for Schedule III–V

Order midazolam and ketamine using standard purchase orders. Upon receipt, the invoice or packing slip (showing drug name, form, strength, quantity, supplier, and date received) serves as the receiving record. These records must be annotated with the date received and initialed by the staff member who checked the delivery.

E. Record-keeping of Receipts

For each controlled substance delivery, immediately log the received quantities into the controlled substance inventory log. File Form 222s and receipts/invoices in chronological order. Schedule II records are stored separately from Schedule III–V records (or clearly flagged) as required by DEA regulations.

F. Stock Quantity Management

Order only quantities needed for legitimate medical use to minimize on-hand inventory. Rotate stock to use older inventory first. If any discrepancies or missing shipments occur, report them to the supplier and DEA immediately and notify the medical director in writing within 24 hours that a discrepancy has been identified.

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3. STORAGE AND SECURITY:

A. Secure Storage Cabinet

All controlled substances must be stored in a securely locked, substantially constructed cabinet or safe at all times when not in active use (per 21 CFR §1301.75 guidelines). The cabinet should be made of metal or wood with a robust lock; preferably a steel narcotics safe anchored or bolted in place.

B. Restricted Access Protocols

Access to the controlled substance cabinet is limited to authorized personnel only. Authorized personnel are the DEA registrant (physician) and specific licensed staff (e.g. ALS providers) designated in writing by the Medical Director (See "personnel" above. A current authorized-access list shall be posted inside the medication room by the medical lead or designee. No other staff or visitors may handle keys or access controlled substances.

C. Key and Code Controls

Keys (physical or digital) to the controlled substance cabinet are kept to a minimum. For electronic keypad locks, issue unique access codes to each authorized user and change codes periodically (at least once per summer/winter season, or upon staff turnover). Immediately retrieve deactivate codes when a staff member is no longer authorized (e.g. termination of employment, revocation of access). A physical key to access the safe will be held only by the medical director and the patrol director. The patrol director is only to use the key if routine means off access are impaired and need is pressing. Any use of the key should be reported immediately to the medical director.

D. Double-Lock

When possible, utilize a double-lock system to protect medication access. Keep the door to the patrol room key-code locked, and if the door must be propped open, the

medication storage room should be locked during that time. Both the patrol room door and the medication room door should be locked after hours.

E. Segregation

Non-controlled medications should be stored separately from controlled medications. Within the controlled drug safe, separate shelves, bins, or boxes for each medication should be used to maintain segregation and prevent confusion.

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4. ADMINISTRATION AND WASTE:

A. Authorized Administering Staff

Only approved patrol staff may dispense or administer these controlled medications to patients. This includes the medical director physician, EMTs, nurses, and paramedics acting on physician orders and protocols. Each authorized staff must complete training on controlled substance handling and sign a form acknowledging the understanding of patrol policies. Two-person verification (e.g. EMT and Paramedic) is recommended for high-risk drugs like fentanyl prior to administration when possible. Due to the limited number of authorized staff and the austere nature of the patrol practice environment, this is not always possible. The volumes of medications carried by each approved provider should be limited to those which may be used on a single patient, and care should be taken to ensure that only the intended dose/volume is administered.

B. Documentation of Each Dose

Every administration of fentanyl, midazolam, or ketamine must be logged as soon as possible after the patient transport/administration in the Controlled Substance Administration Log. This log provides a perpetual record and accountability for every unit administered. It must be kept separate for each drug (e.g. a log for fentanyl, another for midazolam). The record must include:

- Date and time of administration;
- Patient ID. Specifically, the run number should be recorded in the administration log and the administering provider should ensure that the patient name is recorded separately in the run report;
- Medication name, strength and dose administered;
- Name, credentials, and signature of the person administering the dose;
- Remaining quantity of drug (for multi-dose vials);
- Wastage details if applicable (see below).

C.Patient Tracking

In addition to the administration log, record each dose administered in the patient's medical chart/run report (including drug, dose, route, time, and response). Ensure the controlled drug log and the patient chart entry can be cross-referenced by date/time.

D. Dispensing

The dispensation any controlled substance to a patient or other person to take home or use at a later date is strictly forbidden.

E. Wasting Procedure

If the full volume of a single-use vial of medication is not used (for example, only 50 mcg of a 100 mcg fentanyl ampule is needed), the remaining unused portion must be destroyed on-site as soon as possible after delivering the patient to EMS transport or to the Mt

Bachelor Clinic. Destruction of larger volumes of medication is addressed separately below.

Wastage must be done in the presence of a witness. It is preferable that that witness be another ALS provider or a patrol supervisor. If such persons are not immediately available, another patroller, preferably the BLS provider on the same call, can cosign as witness. It is also acceptable for a member of the receiving EMS unit to cosign using their first and last initial as well as their unit number.

Acceptable on-site destruction methods include squirting the leftover medication into a pharmaceutical waste container (e.g. one with absorbent material or into a sharps container if liquid), or mixing it with used coffee grounds/kitty litter in a disposal pouch, making it non-recoverable.

Both the administering staff and the witness sign the controlled substance log, noting the amount administered, the amount remaining, and the amount wasted.

Note that fentanyl and ketamine can persist indefinitely in the environment and water supply. Wasting controlled substances using a sink or toilet drain is not permissible under Oregon law. Waste only into irrecoverable material.

When an irrecoverable material such as an absorbent is saturated, it must be disposed of as pharmaceutical hazardous waste. Please use appropriate medical waste containers in the Mt Bachelor Clinic for disposal.

F. Inventory Update

Immediately adjust the perpetual inventory count in the log after each administration/waste. For instance, subtract the amount given (and wasted) from the running balance. The remaining balance in the vial (if kept for multi-dose vials like midazolam) should also be tracked. If a multi-dose vial is used over several patients, each use is logged and when the vial is finished or expired, that should be noted.

G. Safeguarding during Use

Do not pre-draw or pre-chart controlled drugs far in advance. Prepare medications as close to administration time as possible. Never leave a drawn syringe or unlocked vial unattended. If a dose drawn into a syringe is not used (e.g. procedure canceled), two staff must waste the medication together and log it. All medications in syringes should be labeled with the medication name and concentration if not immediately administered.

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5. UNUSED AND EXPIRED MEDICATIONS:

Proper disposal of controlled substances is critical to prevent misuse. The patrol will follow DEA and state guidelines for disposing of expired, excess, or unusable fentanyl, midazolam, and ketamine.

A. Quarantine and Documentation

Any controlled substance that is expired, contaminated, damaged, or otherwise not suitable for use shall be immediately removed from the active inventory. Such items must be clearly marked and quarantined in a separate, clearly labeled container (locked if possible) away from in-use stock. The item(s) should be labeled “Do Not Use – Awaiting Disposal.” A record must be made in the controlled substance log documenting the drug name, amount, and reason for removal (e.g. expired) and the date. These quarantined drugs must not be

returned to general stock except with the express order of the medical director.

B. Return or Destroy

Arrangements will be made for prompt destruction or return of the quarantined substances. Preferred method is to use a DEA-registered reverse distributor or return the drugs to the original manufacturer or supplier if they accept returns. The reverse distributor will provide documentation of receipt and will handle final destruction (incineration) in compliance with DEA rules. If on-site destruction is necessary (e.g. small quantities of waste), it must be performed in accordance with DEA guidelines (rendering the drug non-retrievable) and witnessed by at least two authorized staff members, with details logged.

Any on-site destruction of controlled substances (aside from routine small waste from single-dose administration) should be reported on DEA Form 41 (Registrants' Inventory of Drugs Surrendered). This form, listing the drugs and quantities destroyed, must be completed, witnessed, and forwarded to DEA as required. Copies of each Form 41 must be retained in the patrol's records for at least 3 years.

C. Recalled or Suspect Drugs

If any controlled substance is subject to a manufacturer recall or is identified as suspect or illegitimate (e.g. possible counterfeit), it must similarly be segregated and documented. Do not use recalled or suspect drugs. These should be treated as quarantined until returned or destroyed, consistent with the disposal procedures.

D. Environmental and Safety Compliance

All drug disposals will be done in a manner that complies with environmental regulations and OSHA safety standards. For instance, disposed liquid should be placed in designated pharmaceutical waste containers (not down the drain), and sharps (needles) in proper sharps containers. The reverse distributor or disposal contractor's instructions will be followed for packaging and shipping any controlled substances slated for destruction.
After disposal actions are completed, the controlled substance inventory must be updated to reflect the removal. The patroller will reconcile the log to ensure the quantity on hand matches the documented inventory minus any dispensed and disposed amounts, as an internal check.

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6. RECORD-KEEPING AND INVENTORY CONTROL

Accurate record-keeping is the cornerstone of controlled substance management. The clinic will maintain a complete and current record of all fentanyl, midazolam, and ketamine stocks. This includes records of receipt, administration/dispensing, and disposal. Key record-keeping practices are as follows:

A. Controlled Substance Log

The patrol shall maintain a written record system dedicated to controlled substances. Our log will contain separate pages (and entries) for each controlled drug (fentanyl, midazolam, ketamine), and each entry will record: the date; run number or internal use (eg destruction); the amount administered, dispensed, or wasted; the amount remaining in stock; and the initials of the person performing the transaction. This creates an audit trail for every unit of drug from acquisition to use or disposal. Wasting must be witnessed as per policy above.

B. Three-Year Retention

All controlled substance records (logs, inventories, invoices, forms) will be kept on file

for a minimum of 3 years as required by Oregon law. These records must be readily retrievable and organized (separate from regular medication records) in case of inspection.

C. Perpetual Inventory and Reconciliation

The patrol will operate a perpetual inventory system for these medication stocks. This means that the log book's running balance should indicate at all times exactly how many vials/ampules/tablets are on hand for each drug. At least monthly (and preferably weekly or with each use), a designated patrol member will reconcile the physical count of each drug with the log balance. Any discrepancy must be investigated immediately. A second individual should verify the count as a witness. Document the date of each inventory count and the initials of who performed it. Additionally, as noted, a formal annual inventory will be conducted at the beginning of each winter season with a record kept listing each controlled substance and the quantity on that date, recorded separately from the running log.

D. Receipt and Disposal Records

In a companion file to the administration log, keep all receiving documents (invoices, DEA 222 forms) and disposal documents (DEA 41 forms, reverse distributor receipts). Oregon's dispensing outlet rules require that all records of receipt and disposal be kept at least 3 years and be available for Board inspection. Maintain these in an organized manner (for example, a binder divided into sections for "Invoices" and "Destructions") for quick reference.

E. Inspections and Audits

The Oregon Board of Pharmacy and Oregon Medical Board have the authority to inspect our controlled substance records and storage on request. The Board of Pharmacy conducts routine inspections of registered drug outlets (including any dispensing practitioner outlet) focusing on acquisition, storage, labeling, and record-keeping. To prepare for inspections, the patrol's responsible provider will self-audit the controlled substance log and storage annually (or more frequently). Any discrepancies or violations noted must be documented, immediately reported to the medical director, and investigated.

F. Compliance with Registration

The medical director will be responsible for ensuring that DEA registration and any applicable Oregon registrations (e.g. as a dispensing practitioner drug outlet, if obtained) will be kept current. DEA certificate will be posted at the site of medication storage.

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7. Protocol for Reporting and Investigation of Controlled Substance Discrepancies

A. Scope and Responsibility

1. **Applicability:** This protocol applies to any employee authorized to handle, administer, waste, inventory or store controlled substances. All discrepancies in records (inventory counts, logs or receipts) relating to fentanyl, midazolam or ketamine are covered. Discrepancies include missing vials, mismatched counts, unexplained overages, or incomplete documentation.

2. **Responsible person**: The medical director is the DEA registrant and has overall responsibility for controlled-substance security and record keeping. The patrol medical lead oversees daily operations and may designate a patroller as lead contact for controlled substance administration.

3. **Authorized investigators:** The medical lead or a designee conducts investigations. Any loss, theft or diversion must be reported to the medical director immediately. Loss due to suspected theft or diversion should involve Mt Bachelor Risk Management department and law enforcement.

B. Detection and Immediate Actions

1. **Routine reconciliation:** A perpetual inventory system must be maintained as described above. Any discrepancy triggers an immediate recount by a second authorized person.

2. **During deliveries**: Upon receipt of any controlled-substance shipment, staff must verify quantities, record them and report missing items to the supplier. If any discrepancies or missing shipments occur, the supplier and the DEA are notified and the medical director informed in writing within 24 hours.

3. **Breakage or spills**: Breakage or spills of two or fewer vials of medication witnessed by two staff members do not constitute significant loss and do not require DEA or Board reporting; however, the circumstances must be documented in the log and signed by the registrant and second witness.

C. Reporting Requirements

Federal and state regulations distinguish between minor errors and significant losses or theft. The following steps must be taken whenever an inventory discrepancy cannot be explained by documentation errors or spills:

1. **Internal notification**: As soon as a discrepancy is discovered, the employee must notify the patrol medical lead and the medical director verbally or in writing. The notification must include: drug name, strength, quantity missing or over, circumstances, and any staff present. The internal report should be made within 24 hours of discovery.

2. **Assess significance:** The medical director evaluates whether the discrepancy constitutes a significant loss by considering factors outlined in 21 CFR §1301.74(c): quantity lost, specific drug involved, whether the loss is associated with a specific person or activity, any pattern of losses, diversion potential, and local trends. Any theft or significant loss must be reported to DEA and the Oregon Board of Pharmacy within 24 hours of the event; minor bookkeeping errors corrected upon reconciliation do not require external reporting. If the medical director cannot be contacted within this time frame to make such a determination, the determination should be made by the director of the ski patrol in consultation with the medical lead.

3. **DEA notification:** Federal regulations require that the DEA registrant or authorized contact with power of attorney to notify the DEA Field Division Office in writing within one business day of discovering any theft or significant loss of controlled substances and file a complete and accurate DEA Form 106 (Report of Theft or Loss of Controlled Substances) via the DEA online system. The form must be submitted within 45 days of discovery. Even if the missing drugs are subsequently recovered, the report is still required
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4. **Oregon Board of Pharmacy notification**: Under Oregon Administrative Rule 855-041-1030, a drug outlet must notify the Board of Pharmacy within one business day of a significant drug loss or any violation related to drug theft. When a DEA Form 106 is filed, a copy must also be sent to the Board of Pharmacy. The Board expects an initial email notification using the subject line “Controlled Substance Loss Notification” and a follow-up once the investigation is complete. The patrol should email notifications to

pharmacy.druglossreporting@bop.oregon.gov.

5. Law enforcement: If theft or diversion is suspected, the medical director or POA must contact local law-enforcement authorities to initiate a criminal investigation.

6. Documentation retention: All reports (internal notes, DEA Form 106, Board communications) must be retained for at least three years as part of the controlled-substance record system.

D. Investigation Procedures

1. Initial inquiry

i. Secure the supply: Immediately restrict access to the affected inventory by locking the controlled-substance cabinet and limiting keys or access codes until counts are reconciled. Document names of all individuals with recent access.

ii. Review records: Compare the perpetual log against physical counts, usage logs, delivery invoices and waste records to identify where the discrepancy occurred. Verify that each line entry includes date, run number, dose administered, remaining quantity, and signatures.

iii. Interview staff: Conduct confidential interviews with personnel who had access to the drugs during the period in question. Focus on routine practices, unusual events, or potential miscounts. Document statements.

2. Determination of cause

i. Unaccounted-for doses: For discrepancies due to documentation errors (e.g., failure to subtract a wasted dose), correct the log and have two authorized persons sign the correction. Provide training to prevent recurrence.

ii. Losses from spill or breakage: Document the event and witness signatures. These do not require external reporting but should be included in the internal investigation.

iii. Suspected diversion or theft: Immediately notify the medical director, law enforcement, DEA and the Board as outlined above. Remove the employee from controlled-substance access pending investigation. Cooperate fully with external investigations.

3.Follow-up and corrective actions

i. After completing the investigation, the medical director should issue a written summary addressing the cause, findings, and corrective actions. This summary must be filed with the controlled-substance records and provided to the Board along with the follow-up report.

ii. Corrective actions may include additional staff training, changes in storage/security procedures, increased frequency of inventory counts, or disciplinary measures. If a staff member violated policy, access may be revoked as described under the existing Personnel section.

iii. Update protocols and provide feedback to staff to prevent future occurrences.