|  |  |
| --- | --- |
| **SSMED-**1206 | Controlled Substance Policy |
| **Version No.** | 1 |
| **Content Owner** | Vikand Technology Solutions, LLC. |

|  |  |
| --- | --- |
|  | **US Drug Enforcement Agency (DEA) Controlled Substance/Medication Schedule Objective**   * 1. Drugs and other substances that are considered Controlled Substances under the Controlled Substances Act (CSA) are divided into five schedules. Controlled Substances/Medications 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 the likelihood of causing a drug dependency if abused.   2. Even if the ship never visits the United States or purchases their Controlled Medications outside the United States, the VIKAND Medical Operations Policy follows the US DEA controlled substance schedule which is considered the best practice. * Controlled Substances & medications are divided into schedules based on specific criteria.   + Schedule I: Controlled Substances that have high potential for abuse (i.e. heroin, LSD, mescaline, and marijuana). The Company’s ships do not stock Schedule I drugs.   + Schedule II: Controlled Medications that have high risk of abuse but have medical use. (Morphine, Demerol, Hydrocodone, Hydromorphone, Fentanyl)   + Schedule III: Controlled Medications with less potential for abuse with medical use. (Tylenol with Codeine, Ketamine, Buprenorphine, Codeine)   + Schedule IV: Controlled Medications with less potential for abuse than Class I, II or III. (Alprazolam, Clonazepam, Lorazepam, Diazepam, Zolpidem, Zopiclone, Midazolam, Cough medication containing Codeine, Diphenoxylate Atropine)   + Non-Scheduled: Diprivan (Propofol) if on formulary is to be treated as a Controlled Medication; however, the DEA does not list this as a scheduled controlled substance. |
|  | **Process for Ordering/Receiving Controlled Substances**  The following procedures are for ALL Controlled Substances regardless if they are purchased outside the United States:   * 1. Annual review of Controlled Substances available to order and minimum/maximum inventory levels will be conducted in accordance with the flag state.   2. Any order above the designated maximum approved level, requires approval by the VIKAND Manager, Shipboard Medical Operations. These requests will only be approved once a clear justification is received from the ship Doctor. Examples include but are not limited to: Grand & World Voyages, remote itineraries and trans ocean crossings.   3. Only the following persons have the authority to approve a controlled substance order: * VIKAND Manager, Shipboard Medical Operations * VIKAND Director, Medical Operations * VIKAND Chief Medical Officer or designee * VIKAND, VP Medical Operations   1. The vendor acknowledges receipt of the order and sends an electronic copy of the invoice and tracking information for shipment of the Controlled Substances to the Ship Medical Department and VIKAND, Manager Shipboard Medical Operations.   2. The Ship Doctor is responsible for tracking the delivery of ALL Controlled Substance. When the ship receives controlled substances, the Ship Doctor must complete ALL the following steps on the SAME day the ship receives the Controlled Substance.   3. NOTE: There are no exceptions to this policy. * Record the date and time the package is received. * Verify all the items on the packing list that accompanies the shipment are included/ received in the shipment. * Crosscheck the electronic invoice from the Vendor against what has been received. Note any missing items or quantity discrepancies on the packing list that accompanied the shipment. * Sign and date the packing list. * Send a scanned copy of the signed packing list to the Manager, Shipboard Medical Operations.   1. If the package is not delivered to the ship as expected—or if there are any missing items, damaged packaging, quantity discrepancies, evidence of tampering or possible theft of Controlled Substance in the shipment—the Ship Doctor must follow the procedures in Section 12.6 Discrepancy or Tampering.   2. Upon receipt of a Controlled Substance order, the Ship Doctor must print a copy of the electronic invoice and staple it to the signed copy of the packing list that was included in the shipment. These copies must be filed in a separate binder titled “Controlled Substance Invoices/Packing Lists.” The electronic invoice contains the cost of the Controlled Medication, which will be required for any discrepancy, missing or tampering report.   3. The Staff Captain or an appropriate senior designee or nurse, if employed on board, must witness, verify, count and sign the amount of each Controlled Medication entered into inventory in the Controlled Medication Record Book. By signing, the designee confirms that the documented count matches the exact amount/count as recorded on the Packing List that accompanies each shipment |
|  | **Records of Controlled Medications**   * 1. Accurate records must be kept of all Controlled Medications purchased, dispensed, wasted or disposed of (including Tramadol and Propofol (Diprivan) if on formulary).   2. Prior to arrival in a country or anytime requested, the Medical Center is required to furnish an updated controlled Substance list for Customs purposes.   3. All Controlled Substance must be recorded in the Controlled Substances logbook and EMR (Seacare) if applicable.   4. All Controlled Medications must be recorded in the Controlled Substances Logbook by pharmaceutical name, the brand name may be added in parentheses.   5. A Controlled Substance inventory COUNT of ALL Controlled Medications must be done on the same day of the week every seven days, regardless of the length of the cruise.   6. If there is no nurse, then the Staff Captain or an appropriate senior designee will be required to participate in the controlled medication inventory count.   7. ALL inventory counts must be documented in the Controlled Substances Logbook on the medication’s respective page, with red ink. |
|  | **Onset of Voyage Inventory**   * If a new Doctor or Nurse joins the ship, an additional controlled substances count must be conducted. The count must always include two people; a newly embarking Doctor or Nurse AND a disembarking Doctor or Nurse. The count is entered on the designated medication page for each drug in the Controlled Medication Record Book. Write the word “COUNT” in the patient name section and the count entry must be documented in red ink. The count is initialed by two (2) members of the ship’s Medical Staff. If there is no nurse on board the Staff Captain or Senior Officer designee will participate in the count and sign with their initials |
|  | **End of Voyage Inventory**   * 1. The Controlled Substance Inventory Report Form must be signed by the Ship Doctor and Staff Captain or Senior Officer designee or Nurse if employed on board.   2. The Controlled Substance Inventory Report Form must be completed by the end of the voyage and submitted with the Voyage Report.   3. The end of voyage Controlled Substance Inventory count must be documented on the Port Maritime Health Declaration Form.   4. In the event where the ship will be out of commission or in dry/wet dock and the medical staff will not be onboard for a selected time period, the Doctor and or Nurse will hand over the chain of custody over to the Master or Staff Captain. A full count will be conducted and recorded as above and the controlled substance key of the Medical Staff will be assigned to the Master or Officer. The Same process will be followed when the Medical Staff return. |
|  | **Procedures for Entries in the Controlled Medication Record Book**   * 1. All Medical Officers and anyone who witnesses entries in the Controlled Medication Record Book (i.e., the Security Officer or Staff Captain for disposal of expired medications\s) must enter their full name, title, signature and initials on the signature log page(s) in the Controlled Medication Record Book.   2. All controlled substances have a batch and lot # assigned. * Every controlled substance received, the batch and lot # for that specific controlled substance must be documented at the top of the page of that specific controlled substance page. * The batch # must always be documented in the dispensed line.   1. Each medication listed must have the strength documented, as well as the number of pills or patches per container or cc/container for liquids.   2. Any time a Controlled Substance is dispensed; the Ship Doctor/Nurse must verify the: * quantity/amount being dispensed per the Ship Doctor prescription, verbal or standing order and verify that against the quantity/amount remaining in inventory in the Controlled Medication Record Book and EMR (Seacare) if applicable. This must be done at the time of dispensing; or in the event of an emergency, as soon as possible thereafter.   1. The dispensing of Controlled Substance requires the witness and initials of both the Ship Doctor and Nurse. In the instance where there is only a Doctor onboard, a second witness and signature are not required UNLESS there is any waste of the substance being administered. If there is waste this must be witnessed by the Staff Captain or Senior Officer designee.   2. Administering a medication and wasting the SAME medication may be documented on the same line.   3. Any errors in recording should be single-lined/crossed out, marked “error” and then initialed.   4. Changing or altering a Controlled Substance entry is NOT permitted. A correction to the log must be made on a separate line, and it must explain the error.   5. Any wastage of Controlled Substance shall be witnessed and co-signed by two (2) members (Ship Doctor, Staff Captain or Nurse) (for example: Wasting 5mg of morphine from a 10mg vial).   6. Any controlled Substance replenishment orders received into inventory must be documented on a new separate line on the page where the Medication is listed.   7. The Doctor and a second Officer (Nurse, Staff Captain or Senior Officer designee) must witness, verify, count and initial that the amount of each Controlled Substance entered into inventory in the Controlled Substances Logbook matches the exact amount/count as received on the Packing List that accompanies each shipment.   8. Anytime a Controlled Substance is destroyed, it must be documented on a separate line on the page where the medication is listed.   9. For all controlled substances Counts, write the word “COUNT” in the space where the patient name is listed. The Count entry must be entered with RED ink to assure it stands out from all other logbook entries.   10. The Ship Doctor is responsible for ensuring that the completed Controlled Medication Inventory Reports and the Controlled Medication Record Book have all the required signatures and confirm there are no errors in the documentation.   11. An annual fleet wide controlled Substance inventory count will be conducted. The date when this will be conducted will be determined by the Manager, Shipboard Medical Operations.   12. A new Controlled Substance Logbook must be started after every annual fleet-wide inventory count even if the old book is not filled. The Manager, Shipboard Medical Operations will provide each ship with a new Controlled Substance logbook each year prior to the fleet wide inventory count.   13. Controlled Substance logbooks are retained on file in the Ship’s Medical Center for a period of three (3) years and must be made available for inspections or audits. After three years the book is to be incinerated on board. |
|  | **Adequate Security Controls**   * 1. Controlled Substances may only be prescribed by the Ship Doctor. When a nurse is on board the nurse may dispense with a Ship Doctor prescription or verbal order from the Ship Doctor. The Ship’s Doctor prescription must be attached to the patient’s file.   2. Controlled Substances listed in Schedules II, III, IV, and V including Propofol (Diprivan) must be stored in a double locked cabinet in the Ship’s Medical Center.   3. Any controlled substances requiring refrigeration must be placed in a lockable refrigerator or within a sealed container within the refrigerator.   4. Controlled Substances may be stored in crash carts or emergency response bags only when the carts &/or response bags have a plastic lock, initialed and dated by the doctor or nurse who checked & counted the controlled drugs and sealed the bag. * Emergency response bag:   + The outside of the emergency response bag must be locked with a plastic log tag #, date sealed and initials of the doctor or nurse.   + Controlled substances inside the emergency response bag must be kept in a separate bag that is locked with a plastic log tag #, date sealed and initials of the doctor or nurse.   + Anytime the nurse or doctor break the seal on the narcotic bag inside the emergency response bag they must conduct as soon as possible a full controlled substance count and then re-seal with a new plastic log tag #, date sealed and initials of the doctor or nurse. * Crash Carts:   + Must be locked with a plastic log tag #, date sealed and initials of the doctor or nurse.   + Must have at a minimum a monthly check list kept in the medical department which includes the log tag #, date sealed, initials of the doctor or nurse who did the daily lock check.   + Anytime the nurse or doctor break the seal on the crash cart they must conduct as soon as possible a full controlled substance count and then re-seal with a new plastic log tag #, date sealed and initials of the doctor or nurse. This must be done even if no controlled substances were used.   1. The doctor or nurse must include the controlled drugs in the emergency response bag and crash cart in the weekly controlled drug count which will require adding a new lock, date sealed and initials of the doctor or nurse.   2. The carts &/or response bags must be stored with the on-duty medic or in a locked room where only assigned individuals have an assigned key to access that room.   3. Medical Officers and Master or Staff Captain will be the only persons with access to the locked cabinet and must always keep the key in their possession.   4. Lost or stolen keys require immediate notification to the Security Officer, Staff Captain, Captain and Manager, Shipboard Medical Operations.   5. If a faulty lock or cabinet is identified at any time, immediately notify the Security Officer, Staff Captain, Captain and Manager, Shipboard Medical Operations. Follow section 8.   6. A Controlled Medication count must be done immediately upon discovery of lost or stolen keys or a faulty lock or cabinet. |
|  | **Discrepancy or Tampering**   * 1. Immediately upon discovering any discrepancies in the count, damaged packaging, evidence of tampering or possible theft of Controlled Medications, the Ship Doctor must notify ALL the following persons: * Ship Nurse if applicable * Security Officer * Staff Captain * Captain * Manager, Shipboard Medical Operations * VIKAND, Chief Medical Officer * VIKAND, Director Medical Operations   1. Within a maximum of six (6) hours of the discovery, the Ship Doctor must fill out the Controlled Medication Discrepancy, Missing or Tampering Report Form in its entirety.   2. An investigation by the Security Officer must be done as soon as practical and should include: * Date and Time of discovery * Date and Time that the Controlled Medication Discrepancy, Missing or Tampering Report Form is completed * Staff interviews, which may include urine drug screen * Review of records from current voyage and previous voyage (if necessary) * Review CCTV footage, if available. * Any additional investigation done to find missing medications must be included in the formal report form.   1. The Doctor must submit the following items as attachments via a confidential email to the persons listed below: * The completed Controlled Medication Discrepancy, Missing or Tampering Report Form. Important Note: All relevant facts and information must be included on this form; do not list them in your email * The Security Officer’s Report * A photocopy of the applicable page(s) of the ship’s Controlled Medication Record Book * A photo of damaged packaging (if applicable) * Mark the email “High importance!” & “Confidential” * Send the full report to the following persons:   + VIKAND Manager, Shipboard Medical Operations   + VIKAND Chief Medical Officer   + VIKAND Director Medical Operations   + Staff Captain   + Master   + Cruise Line Senior Director, Marine, Safety and Environmental Operations   + If the discrepancy/error or damaged package is identified, then the Vendor who supplied the controlled substance and the Vikand Director of Supply Chain must also receive via email the list of attached documents. |
|  | **Proper Disposal of Expired Controlled Medications**   * 1. Disposition of expired medications and controlled medications is handled according to: * Company/Ship policy * Flag State Guidelines * Port Agent licensure   1. Any expired Controlled Medications must be counted as part of the inventory until they are officially destroyed.   2. Destruction of Controlled Medications must follow these procedures: |
|  | **Incineration of Expired Medications – where applicable**   * 1. The Master, Staff Captain and/or Medical Management team are to be notified if expired medications and/or controlled medications are to be incinerated.   2. Expired medications must be disposed and recorded as per the Garbage Management Plan. * Requests for incineration must be forwarded to and approved by the Staff Captain/Staff Captain * Staff Captain shall advise the date and time of incineration as well as the ship location * Incineration of controlled medications must be witnessed by the Staff Captain or Senior Officer Designee * Liquid Medications: Empty liquids onto rag or activate charcoal powder by expressing liquid out of Pre-Filled Syringes (PFS) and/or vials. The empty syringes/vials/needles are placed in the medical sharp container in use in the Medical Center. The cloth is then incinerated. * Pills: This process applies to both blister pack/unit dose and individual pills in bottle. Pills do not need to be removed from blister packs before incinerating. * Witnesses must sign the Incineration Forms verifying they were present and witnessed the incineration of the controlled medication * Incineration Forms must be signed by the:   + Doctor   + Staff Captain   + Or those personnel designated by the Company * Copies of the Incineration Form should be sent to the Medical Center and the Bridge   + Final disposition forms will be signed and maintained in the Medical Center and filed in a designated binder or folder   1. The Security Officer/Staff Captain must verify that the count/description of all items being destroyed matches the line item description in the Controlled Medications Record Book. The Security Officer/Staff Captain must sign the line item. * The expired medication will be entered and subtracted from the Inventory list in the EMR (SeaCare) if applicable. |
|  | **Inventory, Reporting and Review**   * 1. The VIKAND Manager, Shipboard Medical Operations will ensure that an annual inventory count is done on every ship.   2. Inventory counts are triggered by a message from the Company Office.   3. The ship must conduct this count within 24 hours they are notified by the Company Office.   4. The completed Annual Controlled Medications Inventory Count is noted “Annual Controlled Medications Inventory” in the Voyage No. section. The same day the inventory count is conducted, the report is scanned and emailed to the VIKAND Manager, Shipboard Medical Operations.   5. Ships receiving US supplied Controlled Medications may be required to complete an annual report for submission to the DEA. All reports must be maintained in the Company Office for a period of three (3) years. |