

**CONTROLLED SUBSTANCES (PHARMACY STOCK)**

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook provides procedures for maintaining accountability of all controlled substances and compliance with Drug Enforcement Administration (DEA) Regulations.
- 2. SUMMARY OF MAJOR CHANGES.** This VHA Handbook incorporates requirements regarding the perpetual inventory that must be maintained for all controlled substances.
- 3. RELATED DIRECTIVE.** VHA Directive 1108 (to be published).
- 4. RESPONSIBLE OFFICE.** The Chief Consultant, Pharmacy Benefits Management Strategic Health Group (119), is responsible for the contents of this Handbook. Questions may be addressed to 202-273-8429.
- 5. RESCISSIONS.** VHA Handbook 1108.1, dated May 16, 1997, is rescinded.
- 6. RECERTIFICATION.** The document is scheduled for recertification on/or before the last working day of October 2009.

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## CONTROLLED SUBSTANCES (PHARMACY STOCK)

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook defines procedures for the Department of Veterans Affairs (VA) accountability of all controlled substances and compliance with Drug Enforcement Administration (DEA) Regulations.

### 2. AUTHORITY

VA maintains a perpetual electronic inventory of all controlled substances, utilizing the mandated Veterans Health Information Systems and Technology Architecture (VistA) Controlled Substances Software. These items consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated, listed in Title 21 Code of Federal Regulations (CFR) Part 1300:

- a. Schedule II drugs are found in 21 CFR 1308.12.
- b. Schedule III drugs are found in 21 CFR 1308.13. **NOTE:** *VHA considers ketamine as a Schedule III drug.*
- c. Schedule IV drugs are found in 21 CFR 1308.14.
- d. Schedule V drugs are found in 21 CFR 1308.15.

### 3. SCOPE

The scope of this program concerns custody and storage of controlled substances in Consolidated Mail Outpatient Pharmacies (CMOP), pharmacy services, wards, clinics (including Community-based Outpatient Clinics (CBOC)), clinical and research laboratories, and all areas authorized to have Controlled Substances Schedules II to V. **NOTE:** *Elements of this Handbook that specifically apply to non-pharmacy research storage of controlled substances are found in paragraph 14.*

- a. These substances must be inventoried according to DEA regulations as found in 21 CFR 1304. A biennial physical inventory of all controlled substances must be conducted and records maintained in accordance with 21 CFR 1304.11. Biennial physical inventory must be taken every 2 years, and may be taken on any date within the 2-year period of the previous inventory. This inventory must be maintained separately from other inventory records. A separate inventory file must be kept for methadone used for maintenance and detoxification treatment.
- b. The VistA Controlled Substances Software must be used for all controlled substances transactions. The forms mentioned in this Handbook apply to the electronic and the manual forms. A printed copy of VA Form 10-2638, Controlled Substance Administration Record, may be used on rare occasions for documenting the administration of a single dose.

c. Prescriptions and the completed VA Form 10-2320, Schedule II, Schedule III Narcotic and Alcoholics Register, and VA Form 10-2321, Controlled Substance Order, must be retained and securely stored. Disposal must be in accordance with VHA's Records Control Schedule (RCS) 10-1. All controlled substance records must be maintained for 3 years (see National Archives NN-166-175, July 22, 1985, Attachment to RCS 10-1).

d. All prescriptions for controlled substances must be stamped with the letter "C," in red ink, not less than 1 inch high, in the lower right corner, in accordance with 21 CFR 1304.04. **NOTE:** *A waiver from this requirement is identified in 21 CFR 1304.04, if the pharmacy uses an automated system.*

e. A physical inventory of the pharmacy vault, including the Pharmacy Drug Cache, for all schedules of controlled substances must be maintained and verified by Pharmacy Service at a minimum of every 72 hours, excluding those weeks containing a Federal holiday when only two inspections are required. Documentation of the verification must be made on the appropriate VA Form 10-2320, or electronic equivalent. Controlled substances in the emergency drug cache must be inspected every 72 hours, unless a waiver for weekly inspections is approved by the Pharmacy Benefits Management (PBM) Strategic Health Group (SHG). These inventories must be inspected during the monthly, unannounced narcotic inspections.

f. Each facility must limit the number of pharmacy employees who have access to scheduled drugs whether in the vault or working stocks (outside the vault) within a 24-hour period. Pharmacy Chiefs must establish access limits based on workload requirements for dispensing controlled substances. Access to these areas must be monitored through the use of electronic access control systems and optional security cameras.

g. An intern, resident, mid-level practitioner, foreign-trained physician, physician, or dentist on the staff of a VA facility, who is exempted from registration (21 CFR 1301.22), must include the registration number of the VA facility and the special internal code number assigned by the VA facility in lieu of the the practitioner's registration number required by law (21 CFR 1306.05b), on all prescriptions issued. The pharmacist must verify the provider's signature and, once completed, the requirement for the prescription (i.e., authorized practitioner stamped, typed, or hand printed on it, as well as the signature of the physician or authorized practitioner) may be maintained in the electronic prescription record.

#### **4. CONSOLIDATED MAIL OUTPATIENT PHARMACY (CMOP) INVENTORY CONTROL SYSTEM**

VA CMOPs must maintain an inventory control system for all controlled substances utilizing a validated inventory management software program. Any validated software must be able to provide:

a. Retrievable inventory records for all transactions, i.e., receipt and/or dispersal, dispensing, removal, and adjustments to inventory.

- b. Documentation of all transactions with the date, the time, and the User Identification (ID).
- c. All transactions requiring override adjustments to inventory, i.e., removal of outdated inventory, adjustments to inventory, discrepancies, and return to stock, must have a two-person (facilitator and witness) system of documenting the transaction.
- d. Safeguards must be established to ensure the electronic data is secure and of limited access.
- e. Storage procedures must be established for electronic records, including archive procedures and hard copy back-up.
- f. Records and Report functions must be established that can retrieve data within 72 hours, and provide storage capability for a period of no less than 3 years.

## 5. RESPONSIBILITIES

- a. **Veterans Integrated Service Network (VISN) and National CMOP Directors.** The VISN and National CMOP Directors must ensure that a comprehensive system for the management of the controlled substances is maintained.
- b. **Medical Facility Director.** Directors of VA medical, outpatient clinic and CMOP facilities are responsible for establishing an adequate and comprehensive system for controlled substances to ensure the safety and control of the Controlled Substances inventory. The Director must require uniform and complete compliance with VHA policies on controlled substances by appointing a Controlled Substances Coordinator to oversee the inspection and review process.
- c. **Chief, Pharmacy Services, and CMOP Facility Director.** The Chief, Pharmacy Services, and CMOP Facility Director, or designee, are responsible for ensuring that:
  - (1) All pharmacy requirements for receipt, storage, handling, and security of controlled substances are followed.
  - (2) The Controlled Substances Coordinator (appointed by the Director, see VHA Handbook 1108.2) is notified of the need to authorize a designated provider to ensure security, handling, and storage of the controlled substances in any designated area (i.e., Research Facility) not staffed by Nursing or Pharmacy Personnel.
  - (3) All new and current Pharmacy employees view the video “Employee Integrity and Pharmacy Security” as part of employee orientation annually; and that documentation of this viewing is maintained.
  - (4) A validated electronic inventory management software program is maintained as the primary storage mechanism for all records. When a commercial system is utilized, it must be interfaced with the facility VistA system. **NOTE:** *The records must be maintained for a period of 3 years, in compliance with DEA regulations.*

(5) In the temporary absence of the Chief, Pharmacy Service, the facility pharmacist designated as Acting Chief, automatically assumes responsibility for security and control of controlled substances.

(6) When a permanent change in the appointment of a Chief of Pharmacy, or CMOP Facility Director, takes place, a complete inventory must be conducted.

(a) The outgoing and incoming Chiefs of Pharmacy jointly conduct the inventory review.

*NOTE: In the event that only one individual is available, a facility-inspecting official must be appointed to conduct the inventory.*

(b) A record of the inventory is made on VA Form 10-2320 for each drug inventoried; each VA Form 10-2320 must be signed by the outgoing and incoming Chiefs (or Acting Chiefs) and the facility inspecting official.

(7) Any discrepancy is made a matter of record and, if indicated, an investigation is initiated to determine the cause of the discrepancy.

d. **Chief, Nursing Services.** The Chief, Nursing Services, or designee, is responsible for ensuring that:

(1) All requirements for handling, storage, and security of controlled substances are followed.

(2) All required inventory verification is performed in accordance with VHA policy.

(3) Security of controlled substances is maintained in all clinics and ward areas.

(4) The determination and access to controlled substances in all clinics and ward areas are appropriately secure.

e. **Controlled Substances Coordinator.** In areas not staffed by nursing personnel (i.e., research), it is the responsibility of the Controlled Substances Coordinator to identify the designated provider responsible for ensuring the security, handling, and storage of controlled substances.

## 6. ORDERING AND RECEIVING CONTROLLED SUBSTANCES

Medical centers must establish written procedures for the ordering and receipt of controlled substances. These procedures must indicate the individuals from Acquisition and Materiel Management Service (A&MMS) and Pharmacy Service who have the designated authority to order, receive, post, and verify controlled substances orders (see VA Handbook 7127).

### a. **Ordering Controlled Substances**

(1) All controlled substances must be ordered separately from non-controlled substances, and must be ordered in compliance with 21 CFR 1305.

(2) The delivery address on all orders for controlled substances must be a DEA-licensed pharmacy.

b. **Receiving Controlled Substances**

(1) All orders for controlled substances must be delivered directly to the pharmacy in unopened shipping cartons (boxes).

(2) The opening of the cartons and the acknowledgment of receipt of the order must be performed in the pharmacy and witnessed by the accountable officer, or designee, and the responsible pharmacy employee.

(3) Both employees must annotate receipt on the appropriate forms.

(4) The accountable officer, or designee, must verify that receipt of the controlled substance has been posted to pharmacy inventory and must annotate the verification on the appropriate forms.

***NOTE:** Discrepancies are to be reconciled with the accountable officer before items are accepted into the pharmacy inventory.*

## **7. STORAGE OF CONTROLLED SUBSTANCES**

a. All Controlled Substances, Schedule II-V, must be secured as defined in VA Handbook 0730, Appendix B. Storage of bulk controlled substances must be in the main pharmacy vault, or other limited access locked room or cabinet. Controlled substances must not be stored in the warehouse, with the exception of the Pharmacy Drug Cache, which must meet the storage requirements of VA Handbook 0730, Appendix B, and must be under the control of pharmacy services.

b. The working stock of controlled substances must be stored in a locked cabinet or secured cart with electronic access; it must not be dispersed with general pharmacy stock.

c. All outpatient controlled substances awaiting patient pickup must be stored in a locked area or cabinet with electronic access. Employees having access to the locked area are to be limited and documentation of access must be maintained.

d. Each medical center, outpatient clinic, and CMOP must install electronic access control systems in pharmacies to monitor access to controlled substances. This includes vaults and cabinets used for storage of controlled substances within pharmacies, and secured areas utilized for dispensing controlled substances within pharmacies.

e. The following specifications are the minimum requirements for any electronic access control system:

(1) **Access Safeguard.** To prevent learning codes through keypad observation or use of stolen or found access cards.

(2) **Time Sensitive.** The ability to program access by user, by shift, and by day.

(3) **Area Sensitive.** The ability to program access by door and area for each individual user.

(4) **Fail-Safe.** The ability to maintain access security if the system goes down (i.e., bypass key).

(5) **Access Record and/or Audit Trail.** The ability to provide for periodic, or on demand, printout of names, times, and dates of individual accessing.

(6) **User Coverage.** The number of individual access codes that the system can accommodate.

(7) **Individual Access.** Each individual must have an individualized access code. *NOTE: Biometrics may be considered.*

(8) **Tamper-proof Camera System.** A tamper-proof camera system that records all activity is recommended in all pharmacy vaults and working stocks of controlled substances. Either the Police and Security Service or Pharmacy must monitor these camera systems. *NOTE: The standards for digital video systems is included in the VA Security Handbook (VA Handbook 0730).*

## 8. CONTROLLED SUBSTANCES DISPENSING, INPATIENT SERVICES

a. **Prescriptions.** Orders for Scheduled II controlled substances to be administered to patients from unit dose or ward stock must be written for periods not to exceed 7 days. Exceptions may be made if the responsible provider has evaluated the patient's condition and determined there is a need for a longer duration of therapy. In such cases, the provider may prescribe for a period not to exceed 30 days, if the provider indicates a specific length of therapy or number of doses in the individual patient's order. *NOTE: This is usually for long-term care, oncology, and Hospice patients.*

*NOTE: Controlled substances returned from wards and clinics and determined by Pharmacy Service to be suitable for reissue must be returned to stock. The Pharmacy must use the Vista Controlled Substances package to return the inventory to pharmacy stock.*

### b. **Dispensing**

(1) Controlled substances must be dispensed on VA Form 10-2321, prepared in duplicate, or in the electronic equivalent in Vista.

(2) An authorized pharmacy employee must fill orders for controlled substances.

(3) All orders for controlled substances must be requested using the Controlled Substances package in VistA.

(4) The VistA Controlled Substance Package generates a delivery number that corresponds to the request for the drug.

(5) All records for controlled substance dispensing activities must be maintained electronically in the VistA package.

(6) Controlled substances must be dispensed and delivered by the authorized pharmacy employee to wards, clinics, and other areas of use.

(7) On receipt of the controlled substances and the accompanying record forms, the Registered Nurse (RN) or Licensed Practical Nurse (LPN) must:

(a) Check receipts for accuracy with the items and quantity appearing on VA Form 10-2321, or electronic equivalent.

(b) Check the delivery number on VA Form 10-2321 to ensure that the number corresponds to the drug delivered.

(c) Sign and date receipt on VA Form 10-2321.

(8) In the VistA Controlled Substances Package the authorized nurse is required to complete receipt of the drug entitled "Receipt of Controlled Substances From Pharmacy."

(9) On return to the pharmacy, the authorized employee returns the signed VA Form 10-2321, and the records are cleared.

c. **Automatic Replenishment.** Automatic Replenishment is an automated system whereby par levels for a defined inventory are established so that pharmacy service employees may distribute inventory to fulfill the needs of a nursing unit, clinic, or research area.

(1) Appropriate levels consistent with the needs of the using ward or clinic must be established in the VistA Controlled Substances Package.

(2) An authorized pharmacy employee must issue the supply of controlled substances to the ward or clinic. A record of activity must be maintained in the VistA Controlled Substances Package for each item issued.

(3) Pharmacy Service must electronically generate VA Form 10-2321, listing each item to be replenished. VA Form 10-2321 must indicate the name, ward or clinic, strength, and amount of the drug replenished.

(4) A RN, or LPN, must verify, sign electronically in the VistA Controlled Substances Package, and acknowledge receipt of all controlled substances.

(5) Any identified discrepancy in inventory must be reported immediately to the Nurse Manager, or designee, for follow-up and resolution.

(6) Controlled substances returned from wards and clinics and determined by Pharmacy Service to be suitable for reissue must be returned to stock. **NOTE:** *Pharmacy must use the VistA Controlled Substances Package to return the inventory to pharmacy stock.*

d. **Ward or Clinic Stock.** Ward or Clinic Stock is a system where electronic documentation is utilized for requesting controlled substances from pharmacy services.

(1) Appropriate levels consistent with the needs of the using ward or clinic must be requested using the VistA Controlled Substances Package.

(2) Only RNs or Physicians (other than pharmacy staff) are authorized to order controlled substances.

(3) Only an authorized pharmacy employee can issue a supply of controlled substances to ward or clinic. An electronic record of activity must be maintained in the VistA Controlled Substances Package for each item issued.

(4) Pharmacy Service must electronically generate VA Form 10-2321, listing each item to be replenished. VA Form 10-2321 must indicate the name, ward or clinic, strength, and amount of drug replenished, listing each item to be replenished. VA Form 10-2321 must indicate the name, ward or clinic, strength, and amount of drug replenished.

**NOTE:** *In specific instances, or based on patient specific needs (i.e., epidurals, narcotic drips, etc.) hard copies of VA Form 10-2638 may be generated for documentation purposes.*

(5) A RN, or LPN, must verify and sign VA Form 10-2321 electronically in the VistA package, acknowledging receipt of all controlled substances. **NOTE:** *In the rare instances where a preprinted VA Form 10-2321 is used, the RN or LPN may sign the printed form.*

(6) Any identified discrepancy in inventory must be reported immediately to the nurse manager, or designee, for follow-up and resolution.

e. **Automated Point of Care (POC) Machines**

(1) Appropriate levels consistent with the needs of the using ward, or clinic, must be established in the automation software.

(2) An authorized pharmacy employee must issue a supply of controlled substances to the ward or clinic. A record of activity must be maintained in the VistA Controlled Substances Package for each item issued. A RN or LPN must verify the appropriate level in POC, after the Pharmacy restocks.

(3) The Chief, Pharmacy Services, or designee, must ensure that all controlled substances deducted from inventory are entered into the assigned point of care machine. Any identified discrepancy in inventory is to be reported immediately to the Nurse Manager, or designee, for follow-up and resolution.

**NOTE:** *If the discrepancy is not resolved, reports must be made immediately to the Controlled Substance Coordinator, who is responsible for notifying both the Security and Police Service and the facility Director.*

f. **Discrepancies**

(1) If discrepancies exist between the amount ordered and the amount received, the authorized nurse must check with the designated pharmacy employee concerning the amount issued.

(2) If the discrepancy is not resolved, reports will be made immediately, through the Controlled Substances Coordinator, to Police and Security Service and the Facility Director for investigation and follow-up.

**NOTE:** *In those instances where a manual process is required, the completed VA Form 10-2638 is necessary for final disposition. A designated pharmacy employee, prior to filing, must review the completed form for arithmetic errors, losses, or unusual waste.*

## 9. CONTROLLED SUBSTANCES DISPENSING, OUTPATIENT SERVICES

a. Schedule II controlled substances for individual patients must be ordered on VA Form 10-2577F, Security Prescription Form, or other approved form (i.e., State) for Fee Basis or TRICARE patient, and filled in compliance with 21 CFR 1306. **NOTE:** *Pharmacists must enter all prescriptions into VistA.*

b. Schedule III to V controlled substances must be ordered electronically using the Computerized Patient Record System (CPRS) or other approved form (i.e., State-approved) for Fee Basis or Tricare.

c. Partial outpatient dispensing of Schedule II, narcotic substances, may be done as long as it is in compliance with 21 CFR 1306.13.

d. Controlled Substance prescriptions must be filed in accordance with 21 CFR 1304.04.

e. Prescriptions written for controlled substances filled by VA pharmacies may be mailed in accordance with 21 CFR 1300, VA policy and United States (U.S.) Postal Regulations. Prescriptions written for controlled substances cannot be mailed outside the United States.

f. The refilling of a prescription for a Schedule II controlled substance is prohibited in accordance with 21 CFR 1306.12.

- g. Schedule III to V controlled substances may be refilled in accordance with 21 CFR 1306.22.
- h. Partial filling of Schedule III to V controlled substances must be in accordance with 21 CFR 1306.23.
- i. All prescriptions for Schedule III to V controlled substances must be filed electronically; therefore, all information must be maintained in the electronic prescription record. **NOTE:** *These prescriptions can be filled for a maximum of five refills over a 6-month period.*
- j. Exemptions to Controlled Substances dispensing as outlined in 21 CFR 1300, provisions 1306.25 (a), 1306.22 (b), and 1304.04, have been approved for CMOPs by DEA. Since no original or refill prescriptions are physically kept on site at the CMOP, DEA-record filing requirements are not applicable.
- k. Due to the fact that Schedule II drugs, as defined in 21 CFR 1308.12, are not authorized to be stored or dispensed from CMOP facilities, regulatory provisions as outlined in 21 CFR Part 1300 pertaining to this schedule are not applicable.
- l. The label of any drug listed as a "Controlled Substance" in Schedule II, III, IV, or V of the Controlled Substances Act must, when dispensed to or for a patient, contain the following warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."
- m. All prescriptions for Schedule II controlled substances must be dated as of, and signed on, the day issued. They must bear the full name and address of the patient, and the name, address, and DEA registration number of the practitioner. **NOTE:** *Prescriptions will not be filled if they are more than 30 days old when presented.*
- n. Pharmacy Service must verify the identity of the person picking up the outpatient controlled substance prescription for outpatients or patients leaving the medical facility, and must require the signature of such person or their agent. **NOTE:** *A signature trail must be maintained when prescriptions are not dispensed directly to the patient.*
- o. All outpatient prescriptions for controlled substances not picked up at the outpatient window must be returned to stock or mailed to the patient ensuring strict accountability. Pharmacy Service must maintain documentation to identify the disposition (whether mailed, dispensed at the pharmacy window, or returned to stock) of these prescriptions.
- p. Any CMOP Controlled Substances dispensing that is not completed must be documented as to its disposition (i.e., returned to stock, cancelled, etc.). An electronic record of its disposition must be maintained at the CMOP. Inventory changes as a consequence of such disposition must be electronically recorded and, in all instances, the originating VA facility must be notified as to the controlled substances dispensing status.

q. Prescriptions for controlled substances can only be mailed in accordance with 21 CFR 1300, VA policy, and DEA Regulations. The shipping label attached to all controlled substances packages must have printed, as a return address, the CMOP facility address where the package was created.

r. CMOP facilities that do not process their own mailing, or other authorized delivery methods of shipping, must require documentation of the packages processing from the contracted shipper. **NOTE:** *A reconciliation capability with the CMOP facility of what has been processed is advisable.*

s. All packages delivered to the United States Postal Service (USPS) mail carriers or by contracted shipper services, must have a shipping label attached and be permanently sealed so its contents cannot be removed. Controlled Substance containing packages, processed for mailing or shipping, cannot have any annotation on its shipping label that identifies its contents.

t. Return receipt from USPS is not required for controlled substances. Facilities need to use return receipt, or package delivery tracking from FedEx, United Parcel Service, or the current Government Services Administration (GSA) small package carrier for any patient who reports lost or stolen packages. **NOTE:** *A notation needs to be made in the patient narrative with instructions on delivery preferences.*

u. Schedule III, IV and V controlled substances are normally dispensed in 30-day quantities. Local facilities can elect to dispense multi-month quantities of these controlled substances if approved by the local Pharmacy and Therapeutics (P&T) Committee. In addition to P&T Committee approval, the following requirements must be met to dispense Schedule II opioid controlled substances in multi-month (90 days maximum) quantities.

(1) Criteria for use of multi-month fills for Schedule II opioid controlled substances include:

(a) The patient must have a controlled substance agreement established with a single provider or team for opioid therapy.

(b) The patient must not have a recent history of opioid misuse or deviations from controlled substance agreements.

(c) The patient must have demonstrated a history of compliance with all prescribed medications and all components of the treatment plan, including consultations and referrals.

(d) The patient must be on a stable dose of opioids for at least 3 months and under the care and observation of a single provider, or team, for at least 1 year.

(e) The patient must have demonstrated responsibility for managing the opioid therapy by working closely with a single provider, or team, and adhering to the prescribed therapy (i.e., no Emergency Room (ER) visits for chronic pain, no walk-ins for early urgent fills, no unauthorized fills from other providers or facilities, etc.).

(f) The provider must discuss and document in the progress notes the potential risk of theft or robbery, and the strategies the patient must use to reduce the risk of loss, misuse, or theft of these products. If theft or robbery occurs, the patient is not eligible for multi-month fills for a minimum of 3 years from the occurrence.

(g) The patient is subject to random urine and/or blood screens, random pill counts based on the controlled substance agreement, and the judgment of the provider and/or treatment team.

(2) Multi-month fills of Schedule II opioids are absolutely contraindicated in the following situations:

(a) A patient with a documented history of aberrant drug-related behavior, drug abuse, addiction, or diversion.

(b) A patient with a current history of deviations from controlled substance (pain) agreements.

(c) A patient who was not authorized by the primary pain management provider to receive refills from another facility or provider.

(d) A patient being treated for opioid dependence.

(e) A patient whose opioid dose has not stabilized for at least 3 months.

(f) A patient with a positive urine and/or blood screen for unauthorized substances (including alcohol) in the past 3 years.

(g) A patient who has reported lost or stolen controlled substance medication in the past 3 years.

(h) A patient who has refused to submit to a random urine or blood screen when requested by the provider.

(i) A patient who has a pattern of missing scheduled appointments for pain management.

(j) When, for any reason, the provider is uncomfortable prescribing a quantity greater than 30 days supply.

(3) The required monitoring plan, and the responsibilities for facilities that approve the use of Schedule II opioid multi-month fills are:

(a) The facility's controlled substance inspection program must include a random review of 10 percent of the patients on Schedule II opioid multi-month fills each quarter to verify:

1. Signed controlled substance agreements are in place.

2. Refill dates for patients reviewed show no trends of early fills, etc.
  3. Random urine and/or blood screens are negative.
  4. There is a progress note regarding risk of theft and robbery.
  5. Dosage remains stable.
  6. There is no evidence of: unauthorized visits to ER, drug seeking behavior, etc.
  7. The national PBM monitor on controlled substances does not identify patients on multi-month fills receiving drugs from other facilities.
  8. There are no progress notes indicating opioid misuse.
- (b) There is documentation in the facility P&T Committee minutes approving multi-month fills for opioid medications.
- (c) A local policy must be in place that clearly outlines criteria for use and non-use of controlled substances, and defines the responsibility for monitoring compliance with those criteria.
- (d) The results of the quarterly monitors are reported to the medical center Director as a component of the Controlled Substance Inspection Program.

## 10. OPIOID TREATMENT PROGRAMS

*NOTE: Facilities must be licensed for this program. See Substance Abuse and Mental Health Service Administration (SAMHSA) guidelines at <http://www.samhsa.gov>.*

### a. **Ordering**

(1) Pharmacy stock requirements of methadone for a maintenance program must be ordered separately from other Schedule II and Schedule III narcotic substances on VA Form 90-2138, Order for Supplies or Services, or VA Form 2237, Request, Turn-in and Receipt for Property or Services.

(2) The oral, liquid dosage form or specially formulated dispersible tablets of methadone must be utilized initially for a treatment program. The final oral dose administered to the patient must be in oral liquid form. *NOTE: Methadone oral tablets may be used once the patient is no longer a risk for diversion from the oral liquid product.*

(3) Methadone for the maintenance treatment program must be stored according to Federal Regulations and VA policy.

**b. Storage and Dispensing**

(1) The Schedule II controlled substances for prescription by providers of the Opioid Treatment Program unit must be stored separately from all other controlled substances and meet the Food and Drug Administration (FDA) regulations for storage.

(2) Methadone for maintenance and detoxification treatment must be dispensed on receipt of VA Form 10-2577F, VA Form 10-1158, Doctor's Orders, or other approved form, written by a physician who is a part of an approved opioid treatment program.

(3) Methadone must be packaged and dispensed in a single dose form conforming to 42 CFR Chapter I, Section 8.12, Federal Opioid Treatment Standards.

(4) Each take home single dose must be dispensed in a child resistant container and must be labeled with the:

- (a) Treatment center's name,
- (b) Address,
- (c) Telephone number, and
- (d) Physician's name.

(5) When dispensing more than one take home dose, the medication must be dispensed as a prescription and conform to all VA regulations. This includes the submission of a written VA Form 10-2577F, VA Form 10-1158, or other approved form. A pharmacist either in the Opioid Treatment pharmacy or in the Outpatient pharmacy must dispense prescriptions for more than one take home dose.

**11. RECORDS AND FORMS**

a. Receiving documents for all controlled substances must be maintained separately from all other receiving records.

b. The VistA Controlled Substances Package is the primary storage mechanism for all forms. ***NOTE:** If completed and manually signed, VA Form 10-2321, for ward stock orders, must be filed separately in a numerical file.*

c. When purchasing a new automated dispensing system, the system must have an interface with the VistA Controlled Substance Package and the Outpatient Pharmacy Program. All current automated dispensing systems must have such an interface with the VistA Controlled Substance Package and the Outpatient Pharmacy Program when the interface becomes available.

d. The completed VA Form 10-2577F, or other approved forms for Schedule II controlled substances dispensed to outpatients, must be filed separately in a numerical file, or according to 21 CFR 1304.04.

e. Each facility must maintain records on personnel authorized access to areas where Scheduled drugs are stored. Prescription filling and record keeping may be delegated to technical personnel under the direct supervision of an assigned pharmacist. This pharmacist must sign all records of receipt and dispensing.

## 12. PROCEDURE IN CASE OF LOSS OF CONTROLLED SUBSTANCES

a. In cases of accidental loss, breakage, or destruction of small quantities of Schedule II to V controlled substances (such as single doses), the appropriate controlled substances record must be balanced, and a brief explanation of the circumstances entered into the electronic inventory management software.

(1) At the earliest opportunity, entries and explanations must be signed by the person responsible for the loss or breakage and must be called to the attention of the immediate supervisor. **NOTE:** *All balance adjustments must be reviewed during the monthly inspection process.*

(2) If the explanation is not considered satisfactory by the immediate supervisor, the incident must be reported to the facility Director for investigation and to implement the action needed to prevent reoccurrence.

b. In case of accidental loss, breakage, or destruction of small quantities of controlled substances, an adjustment to inventory must be recorded into the electronic inventory management software program.

(1) The use of a two-person (facilitator and witness) signature system for documentation must be strictly enforced on all adjustments or discrepancies.

(2) The inventory management program allows a brief explanatory statement to be entered electronically with the record.

c. In cases of recurring shortages, loss of significant quantities of Schedule II-V substances (several doses), or if there is indication of theft, a report must be made to the facility or National CMOP Director, and a DEA Form 106, Report of Theft or Loss of Controlled Substances, must be completed in accordance with 21 CFR 1301.74. The inspecting official must report such losses disclosed during monthly inspections to the Controlled Substance Coordinator, who forwards the information to the facility Director. In addition, VA Form 1217, Report of Survey, must be prepared to substantiate adjustment actions in accordance with VA Handbook 7125. **NOTE:** *A copy of the report detailed in subparagraph 12f may be attached to VA Form 1217 to complete the report.*

d. Any suspected theft, diversion, or suspicious loss of drugs must be immediately reported to the Controlled Substances Coordinator, who notifies the facility or Pharmacy CMOP Director.

e. The facility or CMOP Director must, in turn, notify the Police and Security Service, and the Office of the Inspector General (Office of Investigations). In addition, the CMOP Director must submit a completed DEA Form 106 to DEA (see subpar. 12c).

f. All facilities must report the theft, loss, or suspected diversion of any controlled substance, or high-value drug, through the Network Director or National CMOP Director to the Chief Consultant, PBM SHG (119). The following information must be included in this report:

- (1) Date(s) or approximate date(s) of each incident.
- (2) Description of each action planned or taken to prevent future loss and/or theft of drugs.
- (3) Date each action in subparagraph 12e was completed.
- (4) For each incident in subparagraph 12e provide:
  - (a) Generic name of each controlled substance schedule, if appropriate, and the total quantity for each drug stolen or lost.
  - (b) Date on which VA initially became aware of theft or loss.
  - (c) The means by which VA first became aware of the theft or loss.
  - (d) The agency or service that initially discovered the theft or loss.
  - (e) The agency or service initially reporting the theft or loss to VA.
  - (f) Each agency known to have investigated the theft or loss.
  - (g) List all law enforcement agencies (Federal Bureau of Investigation (FBI), DEA, local, State, VA police, etc.) to which VA reported the incident.
  - (h) Indicate the category of the suspect, if known:
    1. Current VA employee,
    2. Former VA employee,
    3. Current VA patient,
    4. Former VA patient,
    5. Current VA volunteer,

6. Former VA volunteer, or

7. Unknown.

(i) If the suspect identified was a VA employee, provide:

1. Suspect's employment class,

2. Suspect's employment series,

3. Suspect's grade, and

4. Suspect's occupational group.

g. In case of suspected loss by substitution, the medical center Director must direct a qualified analyst to analyze the suspected material. Adjustment must be made in the appropriate record by the facility Director, or designee, for quantities used in the testing procedure. If substitution is confirmed, an immediate investigation must be conducted and the loss must be reported as outlined in subparagraphs 12c and 12d.

h. Upon completion of the investigation, quantities of Schedule II through Schedule V substances lost for analysis, or otherwise removed from stock in connection with the investigation involved, must be dropped from the record with an appropriate written explanation opposite the entry. Records must be balanced and the facility Director, or designee, must sign all entries and explanatory remarks.

### **13. DISPOSITION OF EXPIRED OR EXCESS CONTROLLED SUBSTANCES**

a. All controlled substances returned from ward, clinic, patient, or from pharmacy stock that are determined unusable and are to be destroyed, must be posted on the Controlled Substance Destruction menu in VistA with appropriate information indicated in the Controlled Substance Destruction menu. The narcotics inspector must check the "Drugs on Hold for Destruction" report in VistA and the sealed bags of the unusable controlled substances monthly. The inspector must verify the accountability of the sealed bags. The contents must be verified at the time of destruction or transfer to a DEA-licensed destruction company.

b. Excess controlled substances on wards and clinics must be returned to Pharmacy Service for redistribution, or destruction. Items determined unsuitable for reissue by Pharmacy Service will be accepted in the pharmacy only for storage purposes, prior to acceptance by the DEA-licensed destruction company.

(1) The authorized pharmacy employee must check the alleged controlled substances in the presence of an authorized RN, or other health care professional, and must place each item returned in a separate envelope. The pharmacy employee must follow all procedures outlined in the VistA controlled substances package, including:

(a) The date, name of substance "believed" or "purported" to be returned, and the quantity of the substance must be written in ink or typewritten on each envelope.

(b) Each envelope must be dated, sealed, and signed across the seal by the authorized pharmacy employee and RN.

(c) The closure of the envelope must be reinforced with clear cellophane tape covering the signatures.

(d) The sealed drugs must be stored in the pharmacy safe, or vault, apart from other drugs or current stocks.

(e) The VistA controlled substances package must post the unusable controlled substance in the database.

(2) Excess or unusable controlled substances must be removed from pharmacy's stock at the time of the regular monthly inspection and posted in the Controlled Substance Destruction file in VistA. The date, reason, and amount removed from pharmacy stock must be indicated in the VistA Controlled Substance Package on VA Form 10-2320. The Chief, Pharmacy Service, or designee, and the Controlled Substances Inspecting Official must sign VA Form 10-2320. Each item removed from stock must be placed in an envelope as described, and must be signed by the Pharmacy Service designee and the Controlled Substances Inspecting Official. The electronic VA Form 10-2320 must be stored in the VistA Controlled Substance Package.

(3) At the CMOP, posting to the unusable controlled substances ledger must be by a two-person (facilitator and witness) signature system. The accountable officer is required to act as one of these two people. **NOTE:** *The electronic recordkeeping system must have the means to accommodate a two-person (facilitator and witness) signature system.*

(4) Controlled substances returned by USPS, or other authorized delivery services, must be deemed "unusable inventory." Undeliverable packages returned to the medical facility or CMOP facility must be received into the unusable controlled substances ledger. The contents of these packages must be identifiable as to description, name of the drug(s), and the quantity of each.

(5) Controlled substances not picked up by patients at the pharmacy window must be returned to pharmacy stock, if they are determined suitable for reissue. Electronic VA Form 10-2320 must show the date, prescription number, patient's name, quantity returned to stock, and inventory adjustment. A supervisory pharmacist and a staff pharmacist must sign on the next unused line as witnesses to the transaction. The patient's prescription must be marked "returned to pharmacy stock," dated, and signed by the pharmacist in the VistA Controlled Substance Package.

(6) Controlled substances returned by the patient, or family member, must be placed in an envelope, one item per envelope as described in subparagraph 12b. A supervisory and a staff pharmacist must sign the envelope. All items must be posted in the VistA Controlled Substances Package.

(7) The same procedures for destruction must be followed as outlined in subparagraph 13b(2).

c. When it is necessary to "waste" part of a Schedule II or Schedule III narcotic substance unit on the ward or clinic, two entries must be made.

(1) The first entry must be the dose given (one-half ampule, 25 milligrams (mg), etc.).

(2) The second entry will be the amount wasted (one-half ampule wasted, 25 mg wasted, etc.).

*NOTE: A RN may waste a partial dose of a Schedule II or Schedule III narcotic substance. An authorized nursing employee must witness this wasting. The amount "wasted" must be disposed of in an appropriate manner.*

d. Disposal of excess of expired Schedule III, IV, and V substances must be in accordance with DEA Regulations, 21 CFR 1307.21. The use of a third-party distributor, authorized to destroy controlled substances, is sanctioned.

e. When a distributor authorized to destroy controlled substances is utilized, the transfer of items for destruction need to include, for the record, in writing the: drug name, dosage form, strength, quantity, and date of transfer. The distributor must provide a completed DEA Form 41 to DEA Headquarters. *NOTE: DEA Form 41 is not to be utilized for recording the transfer action.*

f. The unusable controlled substances ledger must be "cleared" of inventory accountability once the disposal of an item has been rendered. When use of a third-party distributor is facilitated, the distributor needs to provide a copy of all Controlled Substances on the ledger that were taken into custody for destruction.

#### 14. CONTROLLED SUBSTANCES IN RESEARCH AREAS

a. **Procurement.** All controlled substances for use in research (animal or human) must be ordered on VA Form 2237 through Pharmacy. All controlled substances must be ordered separately from non-controlled substances. The drugs are to be charged to the appropriate research cost control point.

b. **Issue**

(1) On receipt, Pharmacy Service must issue the drug to the appropriate research area. The drugs are to be charged to the appropriate research cost control point.

(2) Issuance of controlled substances to research areas must be in accordance with the general provisions for dispensing controlled substances outlined in paragraph 8. Persons authorized to receive controlled substances must be designated by the medical center Director, on the advice of the Associate Chief of Staff for Research, or the Chief of Staff.

c. **Control**

(1) One VA Form 10-2638 must accompany each container of drugs issued. **NOTE:** *Research staff must always use a printed copy of VA Form 10-2638.*

(2) Authorized employee(s) in the research area(s) must maintain appropriate records in accordance with the provisions of this Handbook.

(3) VA Form 10-2638 must indicate the experiment number, date, and any other identifying information available to provide satisfactory proof-of-use record for each dose of drug administered. **NOTE:** *VA Form 10-2638, when completed, must be returned to the pharmacy.*

d. **Inspection.** The authorized research staff must make VA Form 10-2638 and the corresponding drug available for monthly inspection.

e. **Storage**

(1) All controlled substances must be secured according to VA Handbook 0730.

(2) Access must be limited to employees specifically authorized in writing to have access to the controlled substances.