

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 Services (119), is responsible for the contents of this Handbook. Questions may be addressed to 202-461-7297.
- 5. RESCISSIONS.** VHA Handbook 1108.1, dated October 4, 2004, is rescinded.
- 6. RECERTIFICATION.** The document is scheduled for recertification on/or before the last working day of November 2015.

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CONTENTS

CONTROLLED SUBSTANCES (PHARMACY STOCK)

PARAGRAPH	PAGE
1. Purpose	1
2. Authority	1
3. Definitions.....	1
4. Scope	2
5. Responsibilities of the Veterans Integrated Services Network (VISN) Director, the National CMOP Director, and the Clinical Research Pharmacy Coordination Center (CRPCC) Director	2
6. Responsibilities of the Medical Center Director	2
7. Responsibilities of the Facility Providers	4
8. Responsibilities of the Chiefs, Pharmacy Services, the CMOP Director, and the CCPRCC Facility Director	4
9. Responsibilities of the Clinical Research Pharmacy Coordination Center (CRPCC) Director	6
10. Responsibilities of the Medical Center Nurse Executive	6
11. Ordering Controlled Substances	6
12. Receiving Controlled Substances	7
13. Storage and Inventory of Controlled Substances	7
14. Controlled Substances Dispensing, Inpatient Services	10
a. Inpatient Medication Orders	10
b. Ward or Clinic Stock	10
c. Automated Point of Care (POC) Machines	11
d. Discrepancies	11
15. Controlled Substances Dispensing, Outpatient Services	12

CONTENTS Continued

PARAGRAPH	PAGE
16. Opioid Treatment Programs	14
a. Ordering	14
b. Storage and Dispensing	15
17. Records and Forms	16
18. Procedure in Case of Loss of Controlled Substances	17
19. Disposition of Expired or Excess Controlled Substances	19
20. Controlled Substances in Research Areas	22
a. Procurement	22
b. Issue	22
c. Control	22
d. Inspection	23
e. Storage	23
 APPENDIXES	
A VA Form 10-2638, Controlled Substance Administration Record	A-1
B VA Form 10-2320, Schedule II, Schedule III Narcotics and Alcohols Register	B-1
C VA Form 10-2321, Controlled Substance Order	C-1
D VA Form 10-2577F, Security Prescription Form	D-1
E VA Form 10-1158, Doctor’s Order Form	E-1
F VA Form 1217, Report of Survey	F-1

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. **NOTE:** *The Consolidated Mail Outpatient Pharmacies (CMOPs) and the Clinical Research Pharmacy Coordinating Center (CRPCC) have individualized inventory management software and are not held to VistA software requirements.* 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 I drugs are found in 21 CFR 1308.11.
- b. Schedule II drugs are found in 21 CFR 1308.12.
- c. Schedule III drugs are found in 21 CFR 1308.13. **NOTE:** *VHA considers ketamine as a Schedule III drug.*
- d. Schedule IV drugs are found in 21 CFR 1308.14.
- e. Schedule V drugs are found in 21 CFR 1308.15.

3. DEFINITIONS

a. **Accountable Officer.** The Chief, Acquisition and Material Management Service, or designee, is the Accountable Officer (AO) at a field facility. At the CMOP facilities, the Logistics Manager or other individual designated by the CMOP Director is the AO; the AO at the CRPCC is designated by the facility Director. The AO's role is to verify the receipt of controlled substances.

b. **Clinical Research Pharmacy Coordinating Center (CRPCC).** The CRPCC, part of the VA Office of Research and Developments' Cooperative Studies Program, provides for the manufacture, packaging, and distribution of all drugs in the Cooperative Studies Program and other affiliated Federal and collaborative research programs.

c. **Controlled Substances Coordinator (CSC).** A CSC, who is appointed by the facility Director, is responsible for the coordination and administration of the controlled substances inspection program. This program includes pharmacy, inpatient units, clinics (including

Community-based Outpatient Clinics (CBOC)), CRPCC, CMOPs, clinical and research laboratories, anesthesia units, and all other areas authorized to have Schedule II to Schedule V controlled substances.

d. **Designated Provider.** The Designated Provider is an individual, authorized to use controlled substances in research, who is appointed by memorandum of the medical center Director to ensure security, handling, and storage of the controlled substances in the research section.

e. **Evidence Bag.** An evidence bag is a clear plastic bag that can be permanently sealed, on which can be annotated a chain of custody for the controlled substance.

f. **Prescription.** The term prescription means an order for a medication which is dispensed to, or for, an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user.

g. **Provider.** For the purposes of this Handbook, a provider is any individual authorized by the medical facility and listed in the VistA provider file to prescribe controlled substances.

h. **Working Stock.** Working stock refers to a small inventory of controlled medications that is removed from the storage safe and stored in an alternate location in pharmacy for immediate access during dispensing activities. This inventory must have electronic access and preferably an automated storage device (e.g., Pyxis, etc).

4. SCOPE

The scope of this program concerns custody and storage of Controlled Substances, Schedules I through V, in VA facilities authorized for storage, distribution, or dispensing. These areas include: pharmacy services, medical facility inpatient units, clinics (including CBOCs), CMOPs, the CRPCC, clinical and research laboratories, anesthesia units, and all other areas authorized to have Schedule I to Schedule V controlled substances. ***NOTE: Elements of this Handbook that specifically apply to non-pharmacy research storage of controlled substances are found in paragraph 20.***

5. RESPONSIBILITIES OF THE VETERANS INTEGRATED SERVICE NETWORK (VISN), NATIONAL CMOP DIRECTOR, AND THE CRPCC DIRECTOR

The Veterans Integrated Service Network (VISN) Directors, the National CMOP Director, and the CRPCC Director must ensure that a comprehensive system for the management of controlled substances is maintained.

6. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR

Each medical center Director is responsible for:

a. Ensuring controlled substances are inventoried according to DEA regulations as found in 21 CFR 1304.

(1) A biennial physical inventory of all controlled substances must be conducted and records maintained in accordance with 21 CFR 1304.11.

(2) Biennial physical inventory may be taken on any date within the 2-year period of the previous inventory.

(3) The annual inventory required by VHA satisfies this requirement. This inventory must be maintained separately from other inventory records of non-controlled medications.

(4) Methadone used for maintenance and detoxification treatment requires a separate registration and thus a separate inventory file.

b. Ensuring the VistA Controlled Substances Software is used for all controlled substances transactions.

(1) All controlled substances ordered from a wholesaler or manufacturer must first be received in the VistA Controlled Substance Package and then transferred to the commercial automated dispensing systems (e.g., Pyxis, OmniCell, etc.) for storage and accountability. **NOTE:** *The forms mentioned in this Handbook apply to the electronic and the manual forms.*

(2) A printed copy of VA Form 10-2638, Controlled Substance Administration Record, also known as the Green Sheet, may be used on rare occasions for documenting the administration of a single dose. **NOTE:** *For the purposes of this Handbook the CRPCC has its own inventory management software and standard forms for controlled substance record keeping. Therefore, it is not held to VistA software requirements.*

c. Ensuring non-electronic prescriptions and non-electronic completed VA Form 10-2320, Schedule II, Schedule III Narcotic and Alcoholics Register, (see App. B) and VA Form 10-2321, Controlled Substance Order, (see App. C) are retained and securely stored.

d. Ensuring disposal of records is in accordance with VHA's Records Control Schedule (RCS) 10-1. All controlled substance records must be maintained for 3 years (see RCS 10-1, Item 119-4).

e. Establishing an adequate and comprehensive system for controlled substances to ensure the safety and control of the Controlled Substances inventory by:

(1) Requiring uniform and complete compliance with VHA policies on controlled substances by appointing a Controlled Substances Coordinator (CSC) to oversee the inspection and review process; and

(2) Authorizing, in areas not staffed by nursing or pharmacy personnel (e.g., research section), a Designated Provider responsible for ensuring security, handling, and storage of all controlled substances.

f. Ensuring there is a written established policy regarding the reconciliation of controlled substances dispensed to automated devices.

7. RESPONSIBILITIES OF THE FACILITY PROVIDERS

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), is responsible for:

a. Including the registration number (facility DEA number and individual provider code assigned by the VA facility) in lieu of the practitioner's registration number required by law (21 CFR 1306.05b), on all controlled substance prescriptions issued.

b. Signing and hand stamping or printing their full name on all paper prescriptions.

8. RESPONSIBILITIES OF THE CHIEFS, PHARMACY SERVICES, THE CMOP DIRECTOR, AND THE CRPCC FACILITY DIRECTOR

The Chief, Pharmacy Services, and CMOP Directors, or CRPCC Facility Director, or their designee(s), are responsible for ensuring that:

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

b. All pharmacy requirements for receipt, storage, handling, and security of controlled substances are followed.

c. All written medical center or facility controlled substance policies, procedures, and records are in compliance with VHA, DEA, and Federal Regulatory requirements (21 CFR Part 1300-1316).

d. The number of pharmacy employees who have access to scheduled drugs, whether in the vault or working stocks and including commercial automated dispensing systems, within a 24-hour period is limited. The Pharmacy Chief or CMOP Directors, or CRPCC Directors must establish access limits based on workload requirements for preparing, managing, and dispensing controlled substances. Access to these areas must be monitored through the use of electronic access control systems and optional security cameras.

e. The medical facility Director 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 (see VHA Handbook 1108.02).

f. All new Pharmacy employees view the video “Employee Integrity and Pharmacy Security” as part of employee orientation; and that documentation of this viewing is maintained in the VA Learning Management System (LMS).

g. An 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 (the CRPCC is exempt from this requirement). The records must be maintained for a period of 3 years, in compliance with DEA regulations.

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

(1) The outgoing Chief or Director and the designated or Acting Chief of Pharmacy or Acting CMOP or Acting CRPCC Director, jointly conduct the inventory review prior to transfer of responsibility. Additionally, the Acting Chief or Acting Director and incoming Chief of Pharmacy or Director are to inventory all controlled substances and jointly conduct the inventory review upon transfer of permanent responsibility. In the event that only one individual is available (e.g., due to illness), a controlled substance inspector must be appointed by the facility CSC to conduct the inventory review.

(2) A record of the inventory must be made on VA Form 10-2320 or an electronically generated inventory sheet for each drug inventoried; each VA Form 10-2320 or electronic equivalent must be signed by both parties (e.g., the outgoing and incoming Chiefs, or Acting Chief).

i. Any inventory discrepancy is made a matter of record and reported to the facility CSC.

j. A current copy of 21 CFR, Part 1300 (to the end) is retained in the Pharmacy or electronically accessible to pharmacy staff.

k. The number of Pharmacy staff assigned the VistA security key PSDMGR, which allows a user to electronically perform controlled substance balance adjustments, is limited; this requirement does not pertain to CRPCC staff. **NOTE:** *The pharmacy staff involved in the monthly review of balance adjustments must not be assigned this security key.*

l. A written policy and procedures for the ordering and receipt of controlled substances is established. These policy and procedures must designate the Acquisition and Materiel Management Service (A&MMS), Pharmacy Service, and facility individuals who have the designated authority to order, receive, post, and verify controlled substances orders (see VA Handbook 7002)

9. RESPONSIBILITIES OF THE CRPCC FACILITY DIRECTOR

The CRPCC Facility Director is responsible for ensuring that:

- a. The CRPCC facility is registered with the DEA as a “research” facility as defined in 21 CFR 1300 to end.
- b. The CRPCC facility is authorized to be involved in the manufacture, testing, packaging, and distribution of schedule I-V Controlled Substances.
- c. Each clinical study involving controlled substances is approved by the institutional Review Board (IRB) and Research and Development Committee at each participating site prior to study drug distribution.

10. RESPONSIBILITIES OF THE MEDICAL CENTER NURSE EXECUTIVE

The Nurse Executive, or designee, is responsible for ensuring that:

- a. All requirements for handling, storage, administration, and waste of controlled substances are followed in all medical center approved storage and dispensing areas under their purview.
- b. All required inventory verification is performed in accordance with local medical center policy.
- c. Security of controlled substances is maintained and the room is appropriately secured in all medical center approved storage and dispensing areas under their purview.

11. ORDERING CONTROLLED SUBSTANCES

- a. All controlled substances must be ordered separately from non-controlled substances, and must be ordered in compliance with 21 CFR 1305 (see subpar. 8j).
- b. The delivery address on all orders for controlled substances must be a DEA-licensed facility location.
- c. On-line electronic ordering of controlled substances will be used in accordance with DEA Regulation.
- d. The CRPCC must provide controlled substances to clinical studies at participating sites through the medical center’s Pharmacy Service at each site.
- e. The CRPCC must seek the approval of the DEA for each type of controlled substance used in an approved protocol and prior to its distribution to participating sites.

12. RECEIVING CONTROLLED SUBSTANCES

a. All orders for controlled substances must be delivered directly to the pharmacy or CRPCC facility in unopened shipping containers or boxes (see subpar. 8j).

b. The opening of the container or box and the acknowledgment of receipt of the order must be performed in the pharmacy or CRPCC facility and witnessed by the AO, or designee, and the responsible pharmacy employee.

c. Both employees must annotate receipt on the appropriate forms or electronic equivalent.

d. The AO, or designee, must verify that the receipt of the controlled substance has been posted to pharmacy inventory in VistA, at the medical facility, or in the facility inventory at the CMOP or CRPCC. Verification must be annotated on the appropriate forms.

e. Discrepancies must be reconciled with the AO before items are accepted into the pharmacy or CRPCC inventory.

13. STORAGE AND INVENTORY OF CONTROLLED SUBSTANCES

a. All Controlled Substances, Schedule I through V, must be secured as defined in VA Handbook 0730. Storage of bulk controlled substances must be in the pharmacy (or CRPCC facility) vault or safe, unless a waiver is approved by the Office of the Chief Consultant, PBM Services. Controlled substances must not be stored in the warehouse, with the exception of the All Hazards Emergency Cache, which must meet the storage requirements of VA Handbook 0730 and must be under the control of pharmacy services.

b. The working inventory of controlled substances must be stored in a locked cabinet, secured cart with electronic access, or commercial automated dispensing system; it must not be dispersed with general pharmacy inventory.

c. Each medical facility, outpatient clinic, CMOP, and CRPCC facility must install electronic access control systems to monitor access to controlled substances. This includes:

(1) Exterior doors to the pharmacy or medication storage area at the CRPCC;

(2) Vaults and cabinets used for storage of controlled substances within the pharmacy or research facility; and

(3) Secured areas utilized for processing or dispensing controlled substances.

d. The CMOP and CRPCC facilities must maintain an inventory management software program for all controlled substances that provides for:

- (1) Retrievable inventory records for all transactions, i.e., receipt and distribution, dispensing, removal, and adjustments to inventory.
 - (2) Documentation of all transactions with the date, the time, and the User Identification (ID).
 - (3) All transactions requiring override adjustments to inventory (e.g., 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. Both must be pharmacy employees.
 - (4) Safeguards to ensure the electronic data is secure and of limited access.
 - (5) Storage procedures for electronic records, including archive procedures and hard-copy back-up.
 - (6) Records and Report functions that can retrieve data within 72 hours, and provide storage capability for a period of no less than 3 years.
 - (7) All controlled substances sent by USPS are to be identified as “Forwarding Services Requested” in the endorsement line. This results in a greater number of prescriptions reaching the patient.
- 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 area 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 (e.g., bypass key).
 - (5) **Access Record or Audit Trail.** The ability to provide for periodic, or on demand, printouts of authorized employee names, times, and dates of individual accessing the location.
 - (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 the pharmacy or facility vaults and all storage areas containing working stocks of controlled substances. Either the Police Service or Pharmacy must monitor these camera systems. *NOTE: The standards for digital video systems are included in the VA Security Handbook (VA Handbook 0730).*

NOTE: Paragraph 13, subparagraphs 13f through 13i, do not apply to the CRPCC facility.

f. A physical inventory of the pharmacy vault, including the Pharmacy Drug Cache (Schedules II and III) and all working stock for all schedules of controlled substances must be maintained and verified by Pharmacy Service at a minimum of every 72 hours. For pharmacies open 7-days a week, three inspections a week are required and not on consecutive days; excluding those weeks containing a Federal holiday when only two inspections are required (3 days apart). When the pharmacy is open 6 days a week or the vault is locked on weekends (with the controlled substance inventory is only accessible 5 days a week) a physical inventory is only required twice weekly (3 days apart). *NOTE: Point of Care Machines or Automated Dispensing Systems that contain pharmacy stock and are located within the pharmacy are subject to these same inventory requirements.*

g. The complete management of the All Hazards Emergency Cache controlled substances as follows:

(1) All schedule II and III controlled substances must be stored in accordance with VA regulation and Title 21 Code of Federal Regulations (CFR) 1300 to end.

(2) All schedule II and III controlled substances must be inspected every 72 hours, unless the facility has received a written waiver from the VA Central Office Pharmacy Benefits Management Services (PBM) office.

(3) All schedule IV and V controlled substances stored in the sealed cache carts and secured in cache space are exempt from the 72-hour inspection requirement; however, the cache cart seal must be inspected weekly to verify it is intact and the seal number is unchanged.

(4) A physical count of all cache designated schedules II through V controlled substances must be completed quarterly.

(5) All controlled substances in a sealed cache cart must be inventoried each time the cart seal is broken or immediately upon discovery of a broken or suspicious looking cart seal.

(6) All controlled substances inventory must be entered into and maintained in the VistA Controlled Substance software as a separate narcotic area of use.

(7) All controlled substances in the cache must be included in DEA's required biennial inventory.

(8) Any loss of a cache controlled substance is immediately reported in accordance with paragraph 18 of this Handbook.

h. All documentation of inventory verification must be made on the appropriate electronically generated inventory sheet (or VA Form 10-2320).

i. 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, in paper or electronic format, and reviewed on a regular basis to identify unwarranted access (e.g., an employee accessing the inventory during scheduled time off or when assigned to a different area of the pharmacy).

14. CONTROLLED SUBSTANCES DISPENSING, INPATIENT SERVICES

NOTE: Paragraph 14 does not apply to the CRPCC facility.

a. **Inpatient Medication Orders.** 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 local medical center policy for rewrites.

b. **Ward or Clinic Stock.** This refers to a system where electronic documentation (automatic replenishment and ward stock software) is utilized for requesting controlled substances from pharmacy services; the requesting process is as follows:

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

(2) Only Registered Nurses (RN), Physicians or Dentists (other than authorized pharmacy staff) are permitted to order controlled substances.

(3) Only an authorized pharmacy employee can issue a supply of controlled substances to local medical center approved storage and dispensing locations. 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 list each item to be replenished; indicating the name, ward or clinic, strength, and quantity.

(5) A RN, or Licensed Practical Nurse (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) VA Form 10-2638 or electronic equivalent is used to document all usage of controlled substances. In those instances where a manual process is required, a review of the completed VA

Form 10-2638 is necessary prior to final disposition. A designated pharmacy employee, prior to filing, must review the completed form for arithmetic errors, losses, or unusual waste.

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

(8) A printed copy of VA Form 10-2638 (Green Sheet) may be used on rare occasions for documenting the administration of a single dose.

c. **Automated Point of Care (POC) Machines.** When a medical center elects to utilize automated dispensing equipment for controlled substances (e.g., Accudose, Omnicell, Pyxis, etc.) the equipment is to be interfaced, when possible, to Medication Administration Records (MAR) in VistA.

(1) Medical center staff may utilize surveillance tools that accompany automated dispensing equipment (e.g., Pyxis, C-Safe), commercial-off-the-shelf (COTS) software (e.g., Pandora), and future versions of VistA's "Ward Drug Dispensing Equipment (WDDE) interface," to identify potential incidents of drug diversion. **NOTE:** *A listing of potential fileman templates that can be run on a local level are identified in the VistA Controlled Substances Inspector's Manual.*

(2) Par levels consistent with the needs of the medical center approved storage area, must be established in the automation software.

(3) An authorized pharmacy employee must issue the supply of controlled substances to the medical center-approved storage area of use. A record of activity must be maintained in the VistA Controlled Substances Package for each item issued. A RN, LPN, or other authorized staff must verify the appropriate level at POC, immediately after the Pharmacy restocks the inventory.

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

(5) There must be a reconciliation of the controlled substances dispensed to automated devices as established in local policy (see subpar. 6f).

d. **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 must be made immediately, through the CSC, to Police Service and the Facility Director for investigation and follow-up.

15. CONTROLLED SUBSTANCES DISPENSING, OUTPATIENT SERVICES

NOTE: Paragraph 15, does not apply to the CRPCC facility.

a. Schedule II controlled substances for individual patients must be ordered on VA Form 10-2577F, Security Prescription Form (see App. D), or other approved form or electronic equivalent as established in local policy and filled in compliance with 21 CFR 1306.

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

c. When on-hand inventory is insufficient to fill the prescription in its entirety, a partial dispensing of controlled substances may be done, as long as it is in compliance with 21 CFR 1306.13 and 1306.23.

d. Controlled Substance prescriptions must be filed in accordance with 21 CFR 1304.04. VA medical centers are exempt from stamping controlled substance prescriptions with a red "C" in accordance with 21 CFR 1304.04, if they utilize the VistA Controlled Substance software package.

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

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

g. Schedule III thru V controlled substances may be refilled in accordance with 21 CFR 1306.22.

h. All prescriptions for Schedule III thru V controlled substances must be filed electronically; therefore, all information must be maintained in the electronic prescription record. These prescriptions can be filled with a maximum of five refills over a 6-month period.

i. 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.

j. 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.

k. 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."

l. All prescriptions for Schedule II controlled substances must be dated as of, and signed on, the day issued; and they must comply with the provider's responsibilities (see par. 7).

m. 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.

n. 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.

o. 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.

p. 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 local medical center address where the prescription was generated.

q. 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.

r. 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. Packages containing a controlled substance, processed for mailing or shipping, cannot have any annotation on its shipping label that identifies its contents.

s. Return receipt from USPS is not required for controlled substances. Facilities need to use special handling (e.g., return receipt or package delivery tracking from USPS, United Parcel Service, or the current Government Services Administration (GSA) small package carrier) for patients with an identified trend for lost or stolen packages. **NOTE:** *A notation needs to be made, by a pharmacist, in the patient narrative with instructions on delivery preferences.*

t. All returned mail, identified to pharmacy services, must be made secure. Local medical center policy must clearly define the processes enacted to ensure that security needs are met.

u. The local medical center's Pharmacy Service needs to rectify controlled substance issues when CMOP mailed prescriptions do not reach their intended destination. If these controlled substances left the pharmacy and cannot be delivered to the intended patient they must be logged for destruction in accordance with paragraph 19.

v. Schedule II controlled substances are to be dispensed in 30-day quantities or less. An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply provided the following conditions are met:

(1) The patient is deemed competent to receive, have possession of, and present each subsequent prescription to the VA pharmacy at the appropriate time;

(2) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(3) The individual practitioner provides written instructions on each prescription indicating the earliest date on which the pharmacy may fill each prescription;

(4) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(5) The patient has a controlled substance agreement established with a single provider or team for chronic opioid therapy (see par. 16); and

(6) The patient demonstrates a history of adherence to the controlled substance agreement to include compliance with all prescribed medications and all components of the treatment plan, including non-pharmacological measures, consultations, and referrals.

w. Schedule III, IV and V controlled substances are normally dispensed in 30-day quantities. Local medical centers can elect to prescribe a 90-day quantity of these controlled substances if approved by the local Pharmacy and Therapeutics (P&T) Committee and documented in their minutes. A local medical center policy must be developed that outlines the criteria for prescribing a 90 day supply. This policy must define the responsibility for monitoring compliance with the established criteria.

16. OPIOID TREATMENT PROGRAMS

NOTE: Medical centers 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 III narcotic substances on VA Form 222, Request for and Notice of Shipment, or electronically using the Controlled Substance Ordering System (CSOS).

(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 diskettes may be used once the patient is no longer a risk for diversion.*

(3) The provision of take-home medications for Methadone Maintenance and Detox Treatment is defined in Regulation 42 CFR Section 8.12. To be eligible for take-home medications according to this schedule a patient must meet the following eight conditions:

- (a) No recent drug use;
- (b) Attends clinic regularly;
- (c) No serious behavioral problems;
- (d) No criminal activity;
- (e) Stable home environment and good social relationships;
- (f) Length of time in treatment (see <http://www.dpt.samhsa.gov/regulations/exrequests.aspx>);
- (g) Assurance that take-home medication will be safely stored; and
- (h) Judgment that the rehabilitative benefit to the patient will outweigh the risk of diversion (42 CFR Part 8.12.i (2) (i-viii)).

(4) The maximum number of days of take-home medications according to Federal Opioid Treatment Regulation (see 42 CFR 8.12) is 31 days. However, this is dependent on the time in treatment (see par. 16).

b. Storage and Dispensing

(1) Methadone for Opioid Treatment Program 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 (see App. E), or other local medical facility-approved form, written by a physician who is an authorized provider 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 dose must be dispensed in a child resistant container and must be labeled with the:

- (a) Treatment center's name,
- (b) The center's address,
- (c) Telephone contact 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 local medical facility-approved form. A pharmacist either in the Opioid Treatment pharmacy or in the Outpatient pharmacy must dispense all prescriptions requiring more than one take home dose.

17. RECORDS AND FORMS

a. Records on personnel authorized access to areas where Scheduled drugs are stored must be maintained at each facility. 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, dispensing and distribution.

b. Controlled substance records (e.g., the Controlled Substance II Order File; the Schedule II and Schedule III Narcotics and Alcohol Register; the Excess Alcohol and Narcotics File; and Controlled Substance Prescriptions) must all be maintained for a 3 year period.

NOTE: In paragraph 17, subparagraphs 17c through 17g do not apply to the CRPCC facility.

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

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

e. All automated outpatient dispensing systems must have an interface with the VistA Controlled Substance Package and the Outpatient Pharmacy Program.

f. All automated inpatient dispensing systems will be made to interface with the inpatient medication profile, Bar Code Medication Administration Record and VistA controlled substance

package if an interface is available and can be accomplished by the Information Technology Section.

g. 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.

18. PROCEDURE IN CASE OF LOSS OF CONTROLLED SUBSTANCES

a. Any suspected theft, diversion, or suspicious loss of drugs must be immediately reported to the CSC, VHA medical center Police Service, and the medical center Director, CMOP Director, or CRPCC Facility Director for investigation and to implement the action needed to prevent reoccurrence. When ongoing diversion is suspected, the first contacts are the medical center Director, CMOP Director, or CRPCC Director, the Office of Inspector General (OIG), and the facility VA Chief of Police.

b. Any suspected theft, diversion or suspicious loss of drugs at the CRPCC facility must be immediately reported to the medical center Director, DEA, and OIG.

c. In cases of accidental loss, breakage, or destruction of small quantities of Schedule II thru V controlled substances (e.g., five dosage forms or less), the appropriate controlled substances record must be balanced, and a brief explanation of the circumstances entered into the electronic inventory management software program.

(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. All balance adjustments must be reviewed by the Chief of Pharmacy, medical center Director, or designee, and reported to the CSC as part of the monthly inspection process.

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

(3) The use of a two-person (facilitator and witness) signature system for documentation must be strictly enforced on all adjustments or discrepancies. Balance adjustments must be done on paper and have two signatures, by individuals authorized in local medical center, CMOP and CRPCC policy, documenting the adjustment. *NOTE: CMOP and CRPCC facilities can make these adjustments with two electronic signatures in their inventory management software.*

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

d. In cases of recurring shortages, loss of significant quantities of Schedule II-V controlled substances (or Schedule I-V at the CRPCC), or if there is indication of theft, a report must be made to the respective medical center Director, National CMOP Director, or CRPCC Facility

Director; and a DEA Form 106, Report of Theft or Loss of Controlled Substances, must be completed in accordance with 21 CFR 1301.74.

(1) The inspecting official must report such losses disclosed during monthly inspections to the CSC, who forwards the information to the medical center or facility Director.

(2) In addition, the AO must complete VA Form 1217, Report of Survey (see App. F), from the information contained on the DEA Form 106. This 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.*

e. The medical center Director, the CMOP Director, or the CRPCC Facility Director must, in turn, notify the OIG and the facility Police Service (if located on VA medical facility grounds). CMOPs or CRPCC not located on VA medical facility grounds must notify VA Central Office Police Service.

f. The theft, loss, or suspected diversion of any controlled substance, or high-value drug, must be reported through the VISN Director, National CMOP Director, or CRPCC Facility Director to the Chief Consultant, PBM Services (119); and in cases involving the CRPCC, the Chief Research and Development Officer. The report must be forwarded to email group “VHAPBH Pharmacy Reporting CS Diversion/Loss,” using email encryption. The following information must be included in the report:

- (1) Date(s) or approximate date(s) of each incident;
- (2) Description of each action planned or taken to prevent future loss or theft of drugs;
- (3) Date each action in subparagraphs 18c. and 18d. was completed;
- (4) In any incident of theft, loss, or suspected diversion, provide the:
 - (a) Generic name and strength of each controlled substance, 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) Means by which VA first became aware of the theft or loss.
 - (d) Agency or service that initially discovered the theft or loss.
 - (e) Agency or service initially reporting the theft or loss to VA.
 - (f) Agencies known to have investigated the theft or loss.
 - (g) List of all law enforcement and agencies contacted (OIG, DEA, Police Service, etc.).

(h) Category of the suspect (if known) when diversion is suspected, for example;

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 the employment series and grade.

g. In case of suspected loss by substitution, the medical facility Director must direct a qualified analyst to analyze the suspected material. Adjustment must be made in the appropriate record by the medical 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 18b and 18f.

h. Upon completion of any investigation, all appropriate records must be balanced.

19. DISPOSITION OF EXPIRED OR EXCESS CONTROLLED SUBSTANCES

***NOTE:** In paragraph 19, subparagraphs 19a; 19b(3), 19b(4), and 19b(5); and 19c do not apply to the CRPCC facility.*

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

b. Excess controlled substances in authorized storage locations (e.g., inpatient ward areas, clinics, research section, CBOCs, and procedure rooms) must be returned to Pharmacy Service for redistribution or destruction. Items determined unsuitable for reissue by Pharmacy Service are accepted in the pharmacy only for storage purposes, prior to destruction or transfer to a DEA-licensed destruction company.

(1) The authorized pharmacy employee must check the alleged controlled substances in the presence of another approved health care professional, then:

(a) Place each item returned into an evidence bag;

(b) Write in ink on the evidence bag the date, name and quantity of the controlled substance (believed or purported to be returned);

(c) Seal the bag; and

(d) Store the sealed medications in the pharmacy safe, or vault, apart from other drugs or current stocks.

(2) The authorized pharmacy employee and health care professional must follow all procedures outlined in the VistA Controlled Substance Package, including:

(a) Completion of the “Hold for Destruction” report in VistA (attaching the document to the bag for future reference); and

(b) Posting the unusable controlled substance in the database.

(3) Expired or unusable controlled substances must be removed from pharmacy or CRPCC stock and posted in the Controlled Substance Destruction file in VistA; CMOP and CRPCC facilities must post to their inventory management software.

(a) The Chief, Pharmacy Services, or designee, and other health care professional using the VistA generated VA Form 10-2321, must identify the controlled substance, the quantity, sign (two signatures) and inscribe “Hold for Destruction” on the VA Form 10-2321.

(b) Each item removed from stock must be placed in an evidence bag as described and signed by two Pharmacy Service designees (facilitator and witness).

(c) The electronic record must be stored in the VistA Controlled Substance Package. The date, reason, and amount removed from pharmacy stock must be indicated in the VistA Controlled Substance Package on VA Form 2320, Daily Activity Log.

(d) Once medication(s) have been identified for destruction in the “VistA CS Destructions” file, number 58.86, DEA Form 41, Registrants Inventory of Drugs Surrendered Report, is to be generated only those substances that are destroyed locally.

(4) The AO, or designee, is to be involved in the controlled substances turn-in to the destruction company or when the destruction is performed on site.

(5) At the CMOP or CRPCC, posting to the unusable controlled substances ledger must be by a two-person (facilitator and witness) signature process. 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.*

(6) Controlled substances returned by USPS, or other authorized delivery services cannot be reused and must be posted in VA Form 10-2321 (or electronic equivalent), "Hold for Destruction" in the VistA controlled substance package. At the CMOP, all returns must be entered into the "Returned Product Tracking Program." At the CRPCC all returns must be entered into their individualized inventory management software.

(7) Controlled substances not picked up by patients at the pharmacy window must be mailed to the patient or returned to pharmacy stock; with appropriate documentation and inventory adjustment.

(8) The VA Pharmacy Service does not accept returned drugs, including controlled substances, from the patient. However, there are instances when, due to an admission, pharmacy is required to store controlled substances until the time of discharge.

(9) If unable to return the stored drugs to the patient (e.g., the patient's death), the same procedures for destruction must be followed as outlined in subparagraph 19b(2).

c. When it is necessary to "waste" part of a controlled substance an entry documenting the usage must include the amount given and the amount wasted.

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

(2) The second entry is the amount wasted (e.g., one-half ampule wasted, 25 mg wasted). All waste from a partial dose of all controlled substances must be witnessed and signed by authorized health care professionals (facilitator and witness). The amount "wasted" must be disposed of in an appropriate manner according to local medical center policy.

d. Disposal of excess or expired controlled 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, the following in writing: drug name, dosage form, strength, quantity, and date of transfer. The distributor must provide a receipt for all drug products taken at the time of transfer.

f. The "Hold for Destruction" or other electronic file must be "cleared" of accountable inventory once the disposal of an item has been rendered.

g. The facility AO, or designee, is to be involved in the immediate receipt, inspection of all incoming shipments, turn-in and disposal process of all controlled substances.

20. CONTROLLED SUBSTANCES IN MEDICAL CENTER RESEARCH AREAS

a. **Procurement.** All controlled substances for use in research (animal or human) conducted on VA property or facilities must be ordered through and received by Pharmacy Service. When approved VA research is conducted at an affiliate institution or other non-VA location, the local Chief of Pharmacy Services must be consulted to determine whether controlled substances are to be obtained through the VA pharmacy. The research section is to initiate the purchase order with the designated fund control point and forward it to pharmacy for authorization. All controlled substances purchases must be ordered separately from non-controlled drugs.

(1) Controlled substances needed by the Attending Veterinarian for the treatment and care of laboratory animals or needed by an investigator to conduct animal research approved by the Institutional Animal Care and Use Committee (IACUC) must be procured by a local VA pharmacy unless prohibited by Federal regulations or VA policy.

(2) Circumstances in which controlled substances are needed for animal research, but cannot be procured locally need to be brought to the attention of the Chief Veterinary Medical Officer immediately by the Associate Chief of Staff for Research and Development, or other local administrator.

b. **Issue**

(1) On receipt, Pharmacy Service inventories and issues the drug to the appropriate research section.

(2) Issuance of controlled substances to research areas must be in accordance with the general provisions for dispensing controlled substances outlined in paragraph 14. Persons authorized to receive controlled substances in the research section must be designated in writing by the Medical Center Director, on the advice of the Associate Chief of Staff for Research, or the Chief of Staff.

c. **Control**

(1) If an automated dispensing device is not used in the research area, VA Form 10-2638 must accompany each drug issued.

(2) Authorized employee(s) in the research area(s) must maintain appropriate records in accordance with the provisions of this Handbook (see par. 17).

(3) Documentation of administration on either VA Form 10-2638, or within the automated dispensing system, must indicate the protocol number, date, and any other identifying information available to provide a satisfactory proof-of-use record for each dose of drug administered.

(a) When the supply of medication is exhausted or it is deemed the controlled substance is no longer needed in the research area, the completed VA Form 10-2638 must be returned to the pharmacy within 72 hours.

(b) A designated pharmacy employee, prior to filing VA Form 10-2638, must review the completed form for arithmetic errors, losses, or unusual waste and update the entry in the VistA Controlled Substance Package to denote completion.

d. **Inspection.** The authorized research staff must make VA Form 10-2638 and the corresponding drug available for any monthly unannounced inspection. With the exception of quality control inventory checks of automated dispensing equipment in use in research areas, there is no requirement for interim (shift change, daily, weekly, etc.) inventory counts by research personnel or other hospital personnel beyond the monthly unannounced inspections.

e. **Storage**

(1) All controlled substances must be secured under double lock in accordance with VA Handbook 0730.

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

**SAMPLE OF VA FORM 10-2638, CONTROLLED SUBSTANCE ADMINISTRATION
RECORD**

A sample of Department of Veterans Affairs (VA) Form 10-2638, Controlled Substance Administration Record, can be found on the VA Forms Web site at: <http://vaww4.va.gov/vaforms/>. **NOTE:** *This is an internal VA link not available to the public.* This form must be ordered in paper form the Service and Distribution Center. The Stock number is F01213.



VA form 10-2638.pdf

**VA FORM 10-2320, SCHEDULE II, SCHEDULE III NARCOTICS AND
ALCOHOLS REGISTER**

Department of Veterans Affairs (VA) Form 10-2320, Schedule II, Schedule III Narcotics
and Alcohols Register, can be found on the VA Forms Web site at: <http://vaww4.va.gov/vaforms>

***NOTE:** This is an internal VA link not available to the public.*



VA Form
10-2320-fill.pdf

VA FORM 10-2321, CONTROLLED SUBSTANCE ORDER

Department of Veterans Affairs (VA) Form 10-2321, Controlled Substance Order, can be found on the VA Forms Web site at: <http://vaww4.va.gov/vaforms> *NOTE: This is an internal VA link not available to the public.*



VA Form
10-2321.pdf

SAMPLE OF VA FORM 10-2577F, SECURITY PRESCRIPTION FORM

A sample of Department of Veterans Affairs (VA) Form 10-2577F, Security Prescription Form, can be found on the VA Forms Web site at: <http://vaww4.va.gov/vaforms>

NOTE: *This is an internal VA link not available to the public.*



Sample of VA Form
10-2577F.pdf

VA FORM 10-1158, DOCTOR'S ORDER FORM

Department of Veterans Affairs (VA) Form 10-1158, Doctor's Order Form, can be found on the VA Forms Web site at: <http://vaww4.va.gov/vaforms/medical/pdf/10-2321.pdf> **NOTE:** *This is an internal VA link not available to the public.*



VA Form
10-1158.pdf

VA FORM 1217, REPORT OF SURVEY

Department of Veterans Affairs (VA) Form 1217, Report of Survey, can be found on the VA Forms Web site at: <http://vaww4.va.gov/vaforms/medical/pdf/10-2321.pdf> **NOTE:** *This is an internal VA link not available to the public.*



VA Form 1217.pdf