

INSPECTION OF CONTROLLED SUBSTANCES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides procedures for implementing a Controlled Substance Inspection Program.

2. SUMMARY OF MAJOR CHANGES: This VHA Handbook incorporates requirements regarding the implementation of a Controlled Substance Inspection Program, and the responsibilities thereto.

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 RESCISSIONS: VHA Handbook 1108.2 dated July 23, 1997, is rescinded.

6. RECERTIFICATION: This VHA Handbook is scheduled for recertification on/or before the last working day of August 2008.

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INSPECTION OF CONTROLLED SUBSTANCES

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides procedures for implementing and maintaining a Controlled Substance Inspection Program.

2. DEFINITIONS AND AUTHORITY

Controlled substances subject to inspection consist of drugs and other substances by whatever official name, common, or usual name, chemical name, or brand name designated, that are listed in Title 21 Code of Federal Regulations (CFR) Schedule II 1308.12, Schedules III 1308.13, Schedule IV 1308.14, and Schedule V 1308.15; 21 CFR 1301; and Title 21 United States Code (U.S.C.) 812 and 827.

3. SCOPE

A Controlled Substance Inspection Program must be maintained at all Department of Veterans Affairs (VA) medical facilities, Consolidated Mail Outpatient Pharmacies (CMOP), and Clinics. Areas to be inspected are pharmacy, wards, clinics (including Community-based Outpatient Clinics (CBOC)), CMOPs, clinical and research laboratories, Anesthesia units, and all other areas authorized to have Schedule II to Schedule V controlled substances.

4. RESPONSIBILITIES OF THE MEDICAL FACILITY DIRECTOR

Directors of VA medical facilities, outpatient clinics, and CBOCs are responsible for:

- a. Establishing an adequate and comprehensive system for controlled substances to ensure safety and control of all inventory.
- b. Requiring uniform and complete compliance with VHA policies on controlled substances.
- c. Establishing local written medical facility policy(ies) on the use and inspection of controlled substances.
- d. Appointing a Controlled Substance Coordinator (CSC) responsible for the inspection program.
 - (1) The CSC must not have a connection with any component of the controlled substance program, including procurement, prescribing, dispensing or administering of medications.
 - (2) The CSC duties must be included in the employees position description or functional statement.
 - (3) The CSC must meet the same competencies as the inspectors.

e. Ensuring compliance with the annual program for orientation and training of the inspecting officials.

(1) The inspectors must survey all wards and storage areas containing controlled substances by conducting monthly, unannounced controlled substance inspections ensuring the element of surprise.

(a) No inspector will be assigned to inspect the same area 2 months consecutively.

(b) The inspectors must verify source data (i.e., prescriptions, provider orders, Bar Code Medication Administration (BCMA), and other manual records) to detect potential diversion.

(2) Inspectors need to be appointed for a term not exceeding 3 years. **NOTE:** *The Director needs to formally recognize the coordinator and the inspectors for their efforts at the conclusion of their appointment.*

(3) Documentation on all orientation and training provided, as well as the competency assessments of the inspectors must be maintained.

(4) An adequate number of inspectors must be appointed, in writing, who do not have involvement in drug procurement, prescribing, dispensing and administration.

NOTE: *Pharmacists, nurses, or physicians who work in other areas (i.e., Performance Improvement) having no involvement with medication prescribing, dispensing, or administration may be appointed as controlled substance inspectors.*

f. Ensuring that the current Veterans Health Information System and Technology Architecture (VistA) controlled substance software packages are utilized in all inpatient and outpatient settings.

5. RESPONSIBILITIES OF THE PHARMACY DIRECTOR CMOP FACILITIES

The Pharmacy Director of a CMOP facility is responsible for:

a. Establishing a comprehensive system for controlled substances to ensure safety and control of all inventory.

b. Maintaining a written controlled substances policy and procedures, for a controlled substance inspection program.

c. Establishing a training program similar to the national Inspector training on the specific local software.

d. Ensuring inspectors:

(1) Survey the controlled substances storage and dispensing areas.

(2) Verify inventory stock and records for accuracy

(3) Are utilized to ensure that all written local policies, procedures and records are in compliance with VA, VHA, Drug Enforcement Agency (DEA), and Federal Regulatory requirements pertaining to controlled substances (21 CFR Parts 1300-1316).

(4) Complete orientation and training certification requirements before being assigned duty, and maintain documentation of such certification on file.

(5) Are familiar with the inventory control management software program that is used within the facility to safeguard controlled substances.

e. Appointing a CSC responsible for the inspection program. The CSC must not have any immediate connection with the controlled substance program including procurement, dispensing, or record keeping of controlled substances.

f. Ensuring that the CSC completes appropriate training and certification.

g. Appointing an adequate number of inspectors so that no inspector will be assigned to inspect the program 2 months consecutively; the term for an inspector will not exceed 3 years.

h. Ensuring an adequate number of inspectors are appointed, in writing, who do not have involvement in the direct procurement, processing, checking, or mailing of controlled substances within the facility. For example: Pharmacists never assigned controlled substances responsibilities may be utilized, as well as administrative assistants, secretaries, or medical equipment technicians, etc.

6. RESPONSIBILITIES OF THE MEDICAL FACILITY CHIEF, NURSING SERVICES

The Chief, Nursing Services, or designee is responsible for:

a. Ensuring that all requirements for handling, storage and security of controlled substances under control of nursing are followed.

b. Providing access and support for all assigned inspections in nursing service areas of responsibility.

7. RESPONSIBILITIES OF THE MEDICAL FACILITY CHIEF, PHARMACY SERVICE

a. The Chief of Pharmacy Service, or designee, at the local facility is responsible for:

(1) Ensuring that all requirements in Handbook 1108.1 are followed and that all the necessary information is available to inspectors.

(2) Reviewing, monthly, all narcotic balance adjustments, and reporting any discrepancy to the CSC. The reviewer must not hold the PSD Manager key in the current VistA system.

b. The Chief of Pharmacy Service, and Chief of Acquisition and Materiel Management (A&MM) Service, will keep current copies of 21 CFR, Part 1300 (to end) and ensure these copies are accessible to pharmacy staff.

8. RESPONSIBILITIES OF THE CONTROLLED SUBSTANCE COORDINATOR

a. The CSC is responsible for ensuring that:

(1) The required inventories are completed in each area that stores controlled substances.

(2) The nationally mandated training program for inspectors is implemented.

(3) All monthly inspections are assigned and completed.

(4) A monthly summary of findings (including discrepancies) is provided to the Medical Center Director or National CMOP Director.

(5) All documented complaints, recorded by the patient advocate, relating to possible diversion activities (i.e., shorted quantities, mail prescriptions not received, etc.) are reviewed. This review is to be summarized in the monthly report to the Medical Center Director, or the CMOP Director.

(6) All discrepancies are reviewed and resolved by the area supervisor, and entered into the report.

(7) Unresolved discrepancies are reported to the Medical Center Director, or the National CMOP Director, for possible further investigation.

(8) A quarterly report will be provided to the Medical Center Director, or the National CMOP Director, summarizing any identified discrepancies or problematic trends and potential areas for improvement.

b. The CSC, or the pharmacy liaison, must generate a complete list of the serial numbers of VA Form 10-2638, Controlled Substance Administration Record, by ward, clinic, etc. This list provides all serial numbers to the inspecting officials for use in the monthly checks of controlled substance inventories and records. **NOTE:** *The inspecting officials must have access to the inactive VA Forms 10-2638, those returned to the pharmacy since the last inspection, or the electronic equivalent data in VistA. The records used in monthly inspection may be part of the VistA, automated controlled access dispensing equipment, or both.*

9. RESPONSIBILITIES OF THE INSPECTING OFFICIAL

The Inspecting Officials are to conduct random, unannounced inspections as assigned by the CSC; each inspection must be completed on the day it is initiated. The Inspecting Officials are responsible for:

a. Checking on-hand inventories.

- b. Certifying by memorandum to the CSC, the accuracy of the records and inventory of the controlled substances that they have inspected.
- c. Randomly verifying that there are valid prescriptions or inpatient orders, electronic or hard copy for Class II prescriptions, to support the dispensing activity (see subpar. 10e(1) for the frequency of random verification).
- d. Ensuring that all assigned inspections are completed by the end of the month.

10. PROCEDURES FOR INSPECTION OF THE PHARMACY

a. The Chief of Pharmacy Service, or designee, must be present during the monthly inspection. In the case of CMOP facilities, the accountable control substance pharmacist must be present during the inspection. The physical inventory inspection includes all stock of Schedule II to V controlled substances, outdated stock, and records (VA Form 10-2320, Schedule II, Schedule III Narcotics and Alcohol Register, VA Form 10-2638, VA Form 10-2577 F, Security Prescription Form, and electronic equivalents).

b. The Chief of Pharmacy, or designee, and controlled substance inspector must perform a complete physical count in the pharmacy on the first month of each quarter and a random physical count of a minimum of 10 percent (or maximum of 50) of the line items during the other 2 months. The inspector weighs all unsealed powders and measures all unsealed liquids with a volumetric cylinder.

c. The inspecting official(s) must certify the accuracy of the pharmacy records by dating and initialing VA Form 10-2320, or electronic equivalent for each drug or preparation at the time of inspection. This includes:

- (1) All pharmacy vaults, and secured areas where controlled substances stock exists.
- (2) All pharmacy working stocks of controlled substances.
- (3) The Emergency Drug Cache (physical count quarterly and verify seals monthly).
- (4) All pharmacy based automated dispensing machines.
- (5) All drugs held for destruction (compare with destructions holding report, see subpar. 10g).
- (6) Prescription pads.

d. Do not open individually numbered packages to verify inventory. **NOTE:** *The inspecting official is not to open any sealed packages of controlled substances for actual count unless there appears to be evidence of tampering.*

e. Inventory Checks

(1) The inspecting official verifies and documents on the Pharmacy Controlled Substance Inspection Report that 72-hour inventory checks have been completed in Pharmacy since the last inspection.

(a) Pharmacies open 6 or 7 days per week must complete three inventory checks weekly.

(b) Those pharmacies open 5 days per week must complete two inventory checks weekly.

(c) On weeks containing a Federal holiday only two inventories are required in pharmacies open 6 or 7 days per week.

(2) The inspecting official ensures that all controlled substances have been received and placed into inventory by reviewing the monthly prime vendor invoice summary report and all invoices against the pharmacy drug receipt history report.

f. Outpatient Pharmacy

(1) In the outpatient pharmacy, the inspecting official must randomly select and verify that there is a hard copy prescription (written “wet signature” prescription) for 10 percent (or maximum of 50) of the Schedule II controlled substances dispensed. Electronic entry of the Schedule II controlled substances prescriptions in a DEA-approved physician order entry system must have been previously verified using a Public Key Infrastructure certificate.

(2) The inspector is to identify, from the electronic dispensing log, specific prescription entries and then verify that there is a hard copy prescription.

(3) Inspectors must initial on the daily activity log each entry verified with a hard copy prescription. A copy of the daily activity logs must be included with the inspection report.

g. Drug Destruction

(1) Out of date, or other unusable substances that are returned to the pharmacy will be properly stored and destroyed under the control of pharmacy. The inspecting official verifies that drug destructions are completed at least quarterly, and documents this on the monthly inspection report.

(2) The inspecting official reviews the audit trail for ten randomly-selected drugs for destruction by comparing previous month’s destruction holding reports against the last DEA Destruction Report to ensure accountability is maintained from turn-in to pharmacy until destroyed according to VA procedures, or that the item is turned over to a returns company and validated by a returned receipt.

(3) The inspecting official ensures any drug stock removed from inventory for destruction since the last inspection, is properly logged into the record of drugs awaiting destruction.

11. PROCEDURES FOR THE INSPECTION OF INPATIENT UNITS, CLINICS, AND RESEARCH LABORATORIES:

- a. The ward or clinic nurse manager, or designee, is to be present during the inventory and inspection of controlled substances.
- b. The inspector must perform a complete physical count on all ward, clinics and research areas during the first month of each quarter. A random physical count of a minimum of ten line items must take place during the other 2 months of the quarter. Manual entries must be reconciled on VA Form 10-2638, for each drug or preparation during each inspection.
- c. In the inpatient or clinic setting the inspecting official must verify that there is a hard copy order (electronic or written) for five randomly selected dispensing activities on each unit. On a unit with less than five dispensing activities a minimum of two orders must be reviewed.
- d. The inspectors must validate any two transfers from one controlled substance area to another to ensure that appropriate documentation and transfer.
- e. The Inspector must initial and date VA Form 10-2638 (or electronic equivalent), or enter a personal signature in VistA, verifying accuracy of records on the nursing unit or clinic area.
- f. The inspector must ensure that change of shift counts for non-automated dispensing units and weekly inventory for automated units on all wards and remote storage areas are completed.

12. PROCEDURES FOR THE INSPECTION OF AUTOMATED EQUIPMENT

- a. Where medical facilities use automated dispensing equipment for controlled substances (i.e., Accudose, Omnicell, Pyxis, etc.), the equipment needs to be interfaced, when possible, to Medication Administration Records (MAR) in VistA.
- b. The medical center must have specific written instructions for the inspectors on how to inspect each automated dispensing device.
- c. Each inspector must be assigned an individual password that enables access only in the presence of an authorized user.
- d. A ward or clinic nurse must accompany the inspector during all inspections.
- e. The inspector must perform a complete physical count on all ward, clinics, and research areas during the first month of each quarter. A random physical count of a minimum of ten line items must take place during the other 2 months of the quarter. Manual entries must be reconciled on VA Form 10-2638, for each drug or preparation during each inspection.
- f. Inspectors must reconcile 1 day's dispensing (for each unit) from pharmacy to the automated equipment. They are to utilize the pharmacy dispensing reports to automated equipment, validating what was received into inventory.

g. In the inpatient or clinic setting, the inspecting official must verify that there is a hard copy order (electronic or written) for five randomly selected dispensing activities on each unit.

NOTE: *On a unit with less than five dispensing activities a minimum of two orders must be reviewed.*

h. The inspector must ensure that change of shift counts for non-automated dispensing units and weekly verification for automated units on all wards and remote storage areas are completed.

13. OPTIONAL TOOLS FOR DETECTING DIVERSION

a. The Pharmacy Manager and CSC may expand the scope of the monthly inspections by utilizing the Controlled Substances Monitoring menu in VistA to identify potential problem areas.

b. A listing of potential fileman templates that can be run on a local level are identified in the VistA Controlled Substances Inspector's Manual.

14. DOCUMENTATION OF DISCREPANCY OR LOSS OF CONTROLLED SUBSTANCES

In cases of unresolved discrepancies the inspecting official must provide a report to the CSC, who must make a report of findings to the facility Director or National CMOP Director for appropriate action. **NOTE:** *In the case of an identified discrepancy or diversion, the procedures outlined in VHA Handbook 1108.1, are to be followed.*