

INSPECTION OF CONTROLLED SUBSTANCES

1. **REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive provides procedures for implementing a Controlled Substance Inspection Program.
2. **SUMMARY OF MAJOR CHANGES:** This directive has been updated based on recommendation and questions from the field as well as identified vulnerabilities for diversion. It includes the following changes:
 - a. Information duplicative or not in alignment with VHA Handbook 1108.01 was removed and replaced with a reference to that handbook.
 - b. Definitions have been added and the term “discrepancy” clarified.
 - c. Appendices that contained copies of VHA forms were removed. Forms may become outdated before this directive expires. Current forms are available to all VA staff on the forms Web site: <http://www.va.gov/vaforms/>.
 - d. Under the VA medical facility Director responsibilities, recommendations for Controlled Substance Coordinator (CSC) time commitment have been added and training of inspectors has been moved to the responsibilities of the CSC.
 - e. New responsibilities have been added for Associate Chief of Staff for Research and Service, Division and Product Line Managers.
 - f. CSC responsibilities have been expanded to include training, participation in inspections, clarification of missed inspections; and review of inspection reports.
 - g. Responsibilities and requirements for no involvement in the medication use process of the Controlled Substance Inspector (CSI) have been clarified.
 - h. Inspection requirements for Consolidated Mail Outpatient Pharmacies (CMOP) have been separated from the inspection requirements for VA medical facility pharmacies.
 - i. Controlled Substance Drug Destruction Inspection Requirements have been incorporated into the pharmacy inspection requirements for both CMOP and VA medical facilities.
 - j. Procedures for Inspection of Automated Dispensing Equipment have been incorporated into the appropriate area to include Research section, ward units, clinics and pharmacy managed equipment.
 - k. The requirements to perform invoice review and audit trail on destroyed drugs has been eliminated.

l. Procedures for prescription verification have been changed due to the implementation of e-prescribing for controlled substances.

m. Reconciliation of automated dispensing cabinets has been expanded to include removal of stock.

n. Inspection procedures have been clarified.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management Services (10P4P), within the Office of Patient Care Services is responsible for the content of this directive. Questions may be addressed to 202-461-7362.

5. RESCISSIONS: VHA Handbook 1108.02 dated March 31, 2010 and Chapter 10, Inspection of Controlled Substances (Pharmacy Stock) (M-2, Clinical Affairs, Part VII), Pharmacy Service, are rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of November 2021. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Under Secretary for Health

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INSPECTION OF CONTROLLED SUBSTANCES

1. PURPOSE

This Veterans Health Administration (VHA) directive provides procedures for implementing and maintaining a Controlled Substance Inspection Program. The Controlled Substance Inspection Program provides oversight of controlled substance medications at VA medical facilities and Consolidated Mail Outpatient Pharmacies (CMOP). This oversight helps ensure compliance with Federal regulations, statutes, and VA policy, minimizes the risk for loss and diversion, and enhances patient safety.

AUTHORITY: 21 CFR Schedule I 1308.11, Schedule II 1308.12, Schedule III 1308.13, Schedule IV 1308.14, and Schedule V 1308.15; 21 CFR 1301; 21 U.S.C. 812 and 827; 38 U.S.C. 7301(b).

2. DEFINITIONS

a. **Automated Dispensing Cabinet.** Automated Dispensing Cabinet (ADC) is a computerized drug storage device or cabinet that electronically dispenses medications in a controlled fashion and tracks medication use. They also are called a unit based cabinet (UBC), an automated dispensing device (ADD), an automated dispensing unit (ADU) or an automated dispensing machine (ADM). Manufacturer names for ADCs include Omnicell, Pyxis, Accudose and MedSelect with many others commercially available.

b. **Controlled Substances.** The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of Title 21 United States Code (USC) Controlled Substances Act, Section 802. Title 21 CFR, part 1308, provides a listing of each drug, substance or immediate precursor for each schedule.

c. **Controlled Substance Diversion Vulnerability.** Any deviation from the expected findings that does not involve missing medications but indicates either practice not in conformance with policy or other weaknesses in the system of controls. An example of controlled substance diversion vulnerability would be pharmacy not completing the required inventories. In this example, all medication is accounted for, however, since pharmacy is not meeting the requirements stated in policy to perform inventories vulnerability or risk is introduced into the system. Additional examples are in Appendix A.

d. **Controlled Substance Storage Area.** The controlled substance storage area is a physical location where controlled substances are stored. Typically this would be one unit/ward, clinic or procedure area. For example, ICU would be one controlled substance storage area, Ward 6B would be one controlled substance storage area, and the emergency department would be one controlled substance storage area. If the controlled substance storage area contains multiple ADCs, it would still be considered one area. For example, if the operating room has three ADCs, the controlled substance storage area would be the operating room and all three ADCs should be physically counted on the same day. Inpatient and Outpatient Pharmacy is considered one

controlled substance storage area when located within the same physical space. When inpatient pharmacy is physically located separate from outpatient pharmacy, these may be considered two separate controlled substance storage areas.

e. **Discrepancy**. Any deviation from the expected findings that indicate potential loss, diverted, or missing controlled substance medications. For example, the expected inventory count for a drug is 120 units and the actual count is 90. This would indicate loss or diversion of a controlled substance medication. Additional examples are in Appendix A. There may be two types of discrepancies:

(1) **Resolved Discrepancy**. A discrepancy that, upon further investigation and review of dispensing data and other reports has been resolved and it is determined that there is no evidence of loss, diversion or missing controlled substance.

(2) **Unresolved Discrepancy**. An unresolved discrepancy is a variance that upon further investigation cannot be explained. Unresolved discrepancies that indicate missing medications should be reported as loss/diversion per the requirements in VHA Handbook 1108.01.

3. POLICY

It is VHA policy that a Controlled Substance Inspection Program must be maintained at all Department of Veterans Affairs (VA) medical facilities, Consolidated Mail Outpatient Pharmacies (CMOP), and Community Based Outpatient Clinics (CBOC). Areas to be inspected are pharmacy service, inpatient units, clinics, CMOPs, clinical and research laboratories, anesthesia units, and all other areas authorized to have Schedule I to Schedule V controlled substances. The scope of activities differs significantly between CMOPs and medical facility operations. Therefore, inspection program requirements vary and are targeted towards risk potential based on scope of activities.

4. RESPONSIBILITIES

a. **VA Medical Facility Director**. The VA medical facility Director is responsible for:

(1) Establishing an adequate and comprehensive system for controlled substances to ensure safety and control of all inventories;

(2) Requiring uniform and complete compliance with VHA policies on controlled substances;

(3) Establishing local medical facility policy(ies) on the inspection of controlled substances;

(4) Ensuring that at a minimum, the local medical facility policy addresses:

(a) The requirements in this directive;

(b) A time frame of no longer than 5 business days, for supervisors to respond to CSC requests for information on identified discrepancies; and **NOTE:** *The time frame should be determined with input from supervisors and the CSCs.*

(c) A time Frame of no longer than 3 business days for reporting unresolved discrepancies to the medical facility Director and VA Police or the CMOP Director.

(5) Appointing a Controlled Substance Coordinator (CSC) responsible for the inspection program and assuring the following:

NOTE: *Appointment of more than one coordinator (such as a co-CSC or alternate CSC) is recommended for succession planning, coverage, and program continuity.*

(a) The CSC must not currently be employed in a position in which they procure, prescribe, dispense, or administer medications. Nurses who may be required to administer flu vaccine on an infrequent basis may be appointed as a CSC.

(b) The CSC duties must be included in the employee's position description or functional statement. The Director should discuss the time commitment with the CSC and current supervisor and adjust other duties as necessary to provide adequate time for the CSC to perform the inspection program duties. It is recommended that Complexity Level 1 and multi-divisional facilities employ a full time CSC. Frequent turnover of the CSC, with collateral assignments, can result in a less effective program. **NOTE:** *The duties may be added as an addendum to the position description or functional statement.*

(c) The CSC must have a complete understanding of controlled substance policies and the VHA controlled substance inspection process.

(d) The CSC must be introduced to all appropriate training and complete the Controlled Substance Coordinator Orientation Training Course (available on the VA Talent Management System (TMS) Web site at: <https://www.tms.va.gov/learning/user/login.jsp>) within 30 days of appointment. **NOTE:** *Additional information regarding this requirement is available on the Mandatory Required Training Web site at: vaww.ees.lrn.va.gov/mandatorytraining. This is an internal VA Web site that is not available to the public. Documentation of course completion is maintained in the TMS.*

(e) It is highly recommended the CSC also complete the Controlled Substance Inspector Certification course available on the TMS Web site at: <https://www.tms.va.gov/learning/user/login.jsp>. **NOTE:** *This is an internal VA Web site that is not available to the public. Documentation of course completion is maintained in the TMS.*

(f) The new CSC is to be informed about CSC mail-groups and the national CSC SharePoint site: <https://vaww.visn1.portal.va.gov/toqus/home/ControlledSub/nationalcsc/default.aspx> **NOTE:** *This is an internal VA Web site that is not available to the public.*

(6) Appointing an adequate number of Controlled Substance Inspectors (CSIs), in writing, to a term not to exceed 3 years, who do not have access or involvement in drug procurement, prescribing, dispensing, or administration of controlled substances;

NOTE: CSIs may be reappointed after a 1-year hiatus.

(7) Ensuring that all inspection records are retained for a period of 3 years. At a minimum, records should include: all CSI appointment records and training documentation; inspector worksheets and supporting documentation; and monthly and quarterly reports. **NOTE:** Records may be kept electronically in a database or scanned.

(8) Additional considerations:

(a) The CSI appointment memo or e-mail should contain the date that the CSI will begin serving as an inspector so that the 3 year term appointment may be tracked accurately. This date may be in the future to allow for adequate time for the CSI to be trained.

(b) Pharmacists, nurses, or physicians who work in areas having no access or involvement with controlled substance procurement, prescribing, dispensing, or administration (e.g., Performance Improvement, information technology, etc.) may be appointed as CSIs.

(c) Due to the sensitive nature of the assignment, first priority should be given to those individuals in pay grades GS-6 (or WG-5) and above, with a year or more of Federal Service.

(d) VA medical facility Directors should formally express appreciation to CSIs annually or at the completion of their terms. Awards should be considered in accordance with the guidelines of VA Handbook 5017.

b. **Facility Chief of Staff and Chief Nursing Executive.** The Chief of Staff (COS) and the Chief Nursing Executive (CNE) or their designees are responsible for:

(1) Ensuring that all requirements for handling, storage, and security of controlled substances under control of clinical services are followed.

(2) Providing access and support for all assigned inspections in clinical services areas of responsibility, without prior notice.

(3) Ensuring any detection of drug diversion or tampering is immediately brought forward by clinical service areas to Police and Security Service, Pharmacy Service, and the CSC.

(4) Ensuring CSC requests for information on identified discrepancies are responded to within the time frame defined in local policy.

c. **Associate Chief of Staff for Research.** The Associate Chief of Staff for Research (ACOS-Research) or designee is responsible for:

(1) Ensuring that all requirements for handling, storage, and security of controlled substances under control of research are followed.

(2) Providing the CSI access to all controlled substances stored in research areas without prior notice.

(3) The CSC must be provided with a research staff point(s) of contact that is available during normal tours of duty (8am-4:30pm) to provide access and assist with the inspection in the absence of any investigator.

(4) The CSC must be provided with days and times each researcher is generally available in the lab to facilitate inspection scheduling of the CSI when a researcher is available.

(a) Ensuring any detection of diversion or tampering of controlled substances stored in research is immediately communicated to Police and Security Service, Pharmacy Service, and the CSC.

(b) Ensuring CSC requests for information on identified discrepancies are responded to within the time frame defined in local policy.

d. **Service, Division, and Product Line Managers.** Each Service, Division, or Product line manager is responsible for:

(1) Identifying appropriate staff eligible or supporting those who volunteer to serve as Controlled Substance Inspectors for terms of 3 years.

(2) Administratively excusing CSIs from their daily responsibilities in order to ensure the inspector can complete monthly inspection requirements as assigned.

(3) Administratively excusing CSIs from their daily responsibilities in order to ensure the inspector is able to complete required training.

(4) Reporting missing controlled substances, and all evidence of tampering, theft or diversion, to the CSC, Pharmacy Service, and Police and Security Service by the close of business on the day of discovery.

(5) Ensuring that CSC requests for information on identified discrepancies are responded to within the time frame defined in local policy.

e. **Facility Chief of Pharmacy Services.** The facility Chief of Pharmacy Services or designee is responsible for:

(1) Ensuring that all requirements in VHA Handbook 1108.01 are followed and that all the necessary information is available to the CSC and CSIs.

(2) Identifying the Veterans Health Information Systems and Technology Architecture (VistA) and ADC reports needed for the CSIs to complete the requirement to reconcile controlled substance dispensing to and removal from ADCs and to provide

the appropriate reports to the CSIs for the monthly inspections. **NOTE:** *There are three different VistA reports that provide dispensing activity; Daily Activity Log (in lieu of VA Form 10-2320) [PSD DAILY LOG], NAOU Usage Report [PSD NAOU USAGE], and Pharmacy Dispensing Report [PSD PRINT PHARM DISP]. In collaboration with the CSC the Pharmacy Service representative will establish which report will be provided to the CSIs. This will provide consistency as well as help ensure CSIs are properly trained on how to use the report.*

(3) Providing support and written instructions to the CSC for training of the CSIs on how to access and use the ADC.

(4) Ensuring that the CSC has:

(a) An accurate listing of all ADCs and controlled substance storage areas;

(b) A complete listing of all ADC locations and names to ensure the reconciliation process is conducted on every ADC every month; and

(c) Been notified within 3 business days when a new controlled substance storage area is opened or closed to ensure all areas are inspected every month as required.

(5) Ensuring that a pharmacy staff person is present during monthly inspections of the Pharmacy Service controlled substance inventory to assist in performing the physical count and provide any documents the CSI(s) may need.

(6) Reviewing, on a monthly basis, all controlled substance balance adjustments, and reporting any unresolved discrepancy or suspicious activity to the CSC. **NOTE:** *The reviewer cannot perform inventory balance adjustments at any time.*

(7) Ensuring CSC requests for information on identified discrepancies are responded to within the time frame defined in local policy.

f. **Controlled Substance Coordinator.** The CSC is responsible for ensuring that:

(1) New CSIs complete the Controlled Substance Inspector Certification course available on the TMS during their training period. Documentation of course completion is maintained in the TMS. **NOTE:** *Additional information regarding this requirement is available on the Mandatory Required Training Web page at: vaww.ees.lrn.va.gov/mandatorytraining. This is an internal VA Web site that is not available to the public.*

(2) All CSIs receive initial orientation and training and annual updates regarding problematic issues identified through external surveys, monthly and quarterly reports, and other quality control measures. **NOTE:** *It is recommended updates be provided in an annual face to face meeting; however, email or other means of communication may be used if necessary to ensure that all CSIs receive the information.*

(3) All local orientation, annual training, and e-mail updates are documented and kept on file for a period of 3 years. **NOTE:** *It is recommended that documentation for*

face-to-face meetings be recorded in TMS as an external event. However, paper training records are acceptable.

(4) Competency assessments of the CSIs are performed and documented annually.

(5) All CSIs receive specific, written instructions on how to inspect each automated dispensing cabinets that contains controlled substances.

(6) Each CSI that performs ADC inventories is assigned an individual password for the ADC that enables access only in the presence of an authorized user.

(7) The required inspections are assigned and completed as required by this directive in each area which stores controlled substances each month (see paragraphs 5 through 8). The CSC may assist in inspections when training new inspectors, or validating competency. The CSC should not routinely be scheduled to conduct inspections but may participate in cases of unplanned leave, illness or other emergency to ensure the completion of all monthly inspections. The CSC may also complete an inspection when there is a trend with findings in a particular area.

(a) Although an inspector may be assigned to assist in the inspection process on a monthly basis, they may not inspect the same controlled substance storage area two months consecutively.

(b) To ensure the element of surprise, inspections must not be scheduled consistently the same day and week each month. For example, a controlled substance storage area should not be inspected on the third Thursday for 3 months in a row. Inspection dates are to be randomly selected.

(c) Missed inspections must be included in the monthly report with a corrective action plan to prevent missed inspections in the future.

(d) Acceptable reasons for missing an inspection include:

1. Staff assigned to inspect suddenly retires, or goes out on unplanned leave and the CSC is not notified;

2. Environmental factors (i.e., a natural disaster, bomb notification, fire, chemical spill, power failure, etc.);

3. Equipment (e.g., Pyxis, Omnicell, etc.) malfunction or failure that prevents access to controlled substances;

4. A patient care emergency that prevents accessing the controlled substance storage area; or

5. Quarantine or closure of a particular ward or clinic area.

(e) Should a missed inspection occur, the CSC must make an attempt to have the area inspected prior to the end of the month if the situation resolves.

(8) The completed CSI worksheet and supporting documentation are reviewed to ensure all required elements of the inspection were completed.

(9) A monthly summary of findings (including discrepancies and vulnerabilities) is provided to the Medical Center Director or CMOP Director, Chief of Staff, Chief Nurse Executive, Associate Chief of Staff for Research, Chief of Pharmacy, and Chief of Police and Security. **NOTE:** *Appendix A provides examples of discrepancies and vulnerabilities.*

(10) The Monthly Inspection Report includes all documented complaints relating to possible diversion activities (e.g., shorted prescription quantities, mail prescriptions not received, etc.) at the facility which are recorded by the patient advocate, VA Police, or pharmacy staff. When occurring at a CMOP, these reports are to be recorded by the CMOP Quality Assurance Staff and included in the CMOP CSC Monthly Report to the CMOP Director.

(11) Unresolved discrepancies are reported to either the Medical Center Director and VA Police and Security, or CMOP Director for further investigation within the time frame defined in local policy.

(12) Copies of a "Quarterly Trends Report" are provided, as applicable, to either the VA medical facility or CMOP Director, the Chief of Staff, Chief Nurse Executive, Associate Chief of Staff for Research, Chief of Pharmacy Service, and Chief of Police and Security. The Quarterly Trends report should summarize any identified discrepancies, controlled substance vulnerabilities, problematic trends, and potential areas for improvement. **NOTE:** *It is highly recommended that identified discrepancies and problematic trends are examined and discussed in an inter-professional workgroup format to include at minimum representatives from; Pharmacy Service, Nursing Service, Medical Service, and Police and Security with actions and identification of areas of improvement. The workgroup may be structured under the quality or patient safety committees of the VA medical facility.*

g. **Controlled Substance Inspector.** The CSI is responsible for:

(1) Conducting random, unannounced inspections as assigned by the CSC pursuant to the requirements of this directive (see paragraphs 5 through 8) and local policy. The physical inventory of the controlled substance storage area must be completed on the day it is initiated. Other requirements for the controlled substance storage area such as verification of provider orders or hard copy prescriptions may be completed on a separate day.

(2) Completing the inspection report as defined in local policy and submitting to the CSC. The inspection report must include all identified discrepancies as well as identified areas of vulnerability.

(3) Ensuring that all assigned inspections are completed by the end of the month or by the due date assigned by the CSC.

(4) Notifying the CSC (or designee) and the inspection area manager (e.g., nurse manager, charge nurse, clinic/unit supervisor, Pharmacy Chief/supervisor, CMOP Director) on the day of the inspection of any unresolved discrepancies.

h. **Consolidated Mail Order Pharmacy Director.** The Director of a CMOP is responsible for:

(1) Establishing an inspector training program, similar to the Controlled Substance-Drug Diversion Inspection Certificate course, on CMOP specific processes.

(2) Appointing a CSC to be responsible for coordination of the inspection program, and an adequate number of CSIs. The CMOP Director must assure that the CSC:

(a) Has no connection with any component of the controlled substance program, including the procurement, dispensing or record keeping of controlled substance medications.

(b) Duties are included in the employee's position description or functional statement.

(c) Achieves and maintains comprehensive understanding of controlled substance policies and the VHA controlled substance inspection process.

(d) Completes appropriate training and the "Controlled Substance Inspector Certification" course available on the VA Talent Management System (TMS) website at: <https://www.tms.va.gov/learning/user/login.jsp> prior to appointment. **NOTE:** *Additional information regarding this requirement is available on the Mandatory Required Training Web site at: vaww.ees.lrn.va.gov/mandatorytraining. This is an internal VA Web site that is not available to the public. Documentation of course completion is maintained in the TMS.*

(3) Ensuring the CSC also completes the "Controlled Substance Coordinator Orientation Training Course" available on the TMS.

(4) Appointing, in writing, an adequate number of CSIs who are not involved in controlled substance procurement, dispensing, or record keeping (e.g., pharmacists and technicians never assigned controlled substances responsibilities may be utilized, as well as administrative assistants, secretaries, etc.).

(5) Appointing CSIs to a term not exceeding 3 years; Inspectors may be reappointed after a 1-year hiatus. **NOTE:** *Due to the importance of the controlled substance inspection program, for ensuring accountability and confidence in the management and use of controlled substances, the CMOP Director needs to formally express appreciation to CSIs annually or at the completion of their terms.*

(6) Ensuring all controlled substance storage and dispensing areas are inspected on a monthly basis; verifying all inventory stock and record keeping (i.e., procurement, receipt, dispensing, and inventory [active and outdated]).

(7) Ensuring that CSIs at the CMOP are familiar with the inventory management control software program that is used within the CMOP to safeguard controlled substances.

5. PROCEDURES FOR INSPECTION OF THE MEDICAL FACILITY, HEALTH CARE CENTER, CBOCs, EXTENDED CARE SITE, AND RESIDENTIAL CARE SITE PHARMACIES

a. The Chief, Pharmacy Service, or designee, must be present during the monthly inspections.

b. The Chief, Pharmacy Service, or designee, and CSI must perform a complete physical count for all Schedule II through V controlled substances in the pharmacy during the first month of each quarter and a random physical count of 50 line items (or all if less than 50) during the other 2 months.

(1) If controlled substances are stored in multiple locations in pharmacy (i.e., main vault and working stock outside of vault) only a total of 50 inventory line items must be counted. However, the 50 line items should include a representative sample of medications in each location. For example, the inspector would randomly select 40 items from the main vault inventory print sheet to count and 10 items from the working stock inventory sheet to count.

(2) Pharmacy staff should generate the electronic Inventory Sheet Print report from VistA.

(3) The physical inventory includes all controlled substances stored in the vault; all substances in automated dispensing devices within pharmacy; and working stock stored in pharmacy outside of the vault.

(4) All unsealed powders must be weighed and all unsealed liquids must be measured with a volumetric cylinder unless the container has a graduated scale for volumetric measurement.

(5) Do not open manufacturer sealed packages to verify inventory. **NOTE:** *The CSI is not to open any manufactured sealed packages of controlled substances to verify the actual count, unless there appears to be evidence of tampering. Partial containers that have been re-sealed by pharmacy or containers that pharmacy has prepared from bulk stock must be opened and counted. The CSI may not use the hand-written count of contents noted by pharmacy on the container as the inventory count.*

(6) For the partial count months, the CSI must ensure the drugs are chosen randomly on the Inventory Sheet Print report and represent different schedules (II-V) (i.e., do not choose the first 50 or last 50 drugs).

(7) The CSI must note the counts on the inventory sheet of each drug reviewed; signing and dating the last page. The "Inventory Sheet Print" report must be included in the report to the CSC.

c. The CSI must ensure that any drug removed from inventory for destruction is secured and documented in VistA.

(1) Pharmacy staff should generate from VistA the “Destructions File Holding Report” [PSD DESTRUCTION HOLDING], which lists all drugs awaiting local destruction or turn-over to a reverse distributor.

(2) The CSI must verify there is a corresponding sealed evidence bag containing drug(s) for each destruction holding number on the report.

(3) The sealed evidence bags should not be opened or contents counted unless there are signs of tampering.

(4) The verification of drugs held for destruction should be conducted on the same day as the physical inventory of the vault.

d. A physical inventory of the controlled substances in the Emergency Drug Cache must be completed once each quarter by breaking the locks and physically counting all controlled substances. In each of the 2 months of the quarter in which the physical inventory does not occur, the CSI must check the locks for any evidence of tampering and verify the lock numbers. **NOTE:** *The lock numbers can be verified by comparing the lock number on the container to the pharmacy log of lock numbers.*

e. If the cache medications are stored at a location separate from the pharmacy, the inspection may be completed on a separate day from the pharmacy inspection.

f. The CSI must verify the inventory count of prescription pads the day of the pharmacy inspection.

g. The CSI must verify and document, on the Pharmacy Controlled Substance Inspection Worksheet for pharmacy, that inventory checks have been completed in pharmacy as required in VHA Handbook 1108.01 (or local policy if more stringent than handbook requirements), for the prior month. The CSI must:

(1) Visually review all the inventory sheets for the prior month verifying that all items were counted, the required inventories were completed, and a pharmacy staff member signed and dated the inventory sheet; and

(2) Assure that the VHA All Hazards Cache controlled substance inventory has been reviewed per the requirements of VHA Handbook 1108.01.

h. The CSI must verify written wet signature (non-electronically prescribed) controlled substance prescriptions for the previous month using the following method:

(1) The CSC or designated pharmacy staff person will generate the report of non-digitally signed controlled substance prescriptions for the previous month.

NOTE: Currently this is a fileman report but a national VistA report is under development. When the national VistA report is released, all facilities must use this report.

(2) The CSI must randomly select 50 entries from the non-digitally sign report and verify that there is a hard copy prescription (written “wet signature” prescription) for each entry. **NOTE:** If there are less than 50 entries on the report, the CSI should verify all entries.

(a) The inspector will validate that the patient identifier, drug name, strength, quantity, and provider on the hard copy prescription match the information on the report.

(b) The CSI must initial on the non-digitally signed report each entry verified with a hard copy prescription. This report must be included with the inspection report to the CSC.

i. The CSI or CSC must reconcile 1 day’s dispensing from the pharmacy to every ADC and 1 day’s return of stock to pharmacy from every ADC.

(1) The CSI should randomly choose the date. In cases where there was no dispensing to a specific ADC on that day, another day should be selected for that ADC. **NOTE:** It is recommended the CSI ask the pharmacy liaison what days of the week the ADC is generally re-stocked to help ensure a date is chosen that should include inventory transfers.

(2) The pharmacy liaison or the CSC will provide the ADC reports for re-stocking and de-stocking and the VistA report showing dispensing activity to the ADC. The VistA balance adjustment report may be used to validate the de-stocking (i.e., stock transferred from the ADC back to the pharmacy vault) information.

(3) To perform the reconciliation, the CSI will compare the entries on the ADC report to the entries on the VistA report. Any variation (i.e., mis-matching) of information between the two reports should be reported as a discrepancy for further investigation.

6. PROCEDURES FOR INSPECTION OF INPATIENT UNITS AND CLINICS

a. The unit or clinic manager, or designee (nurse or other licensed individual), is to be present during the inventory and inspection of controlled substances and participate in the physical inventory. **NOTE:** The designee may not be a member of the pharmacy staff.

b. The CSI must:

(1) Perform a complete physical count in all controlled substance storage areas during the first month of each quarter. A random physical count of a minimum of 10 line items (or 100 percent if less than 10) must take place during the other 2 months of the quarter.

(2) For areas that do not store controlled substances in an ADC, print or obtain from the CSC or pharmacy liaison the VistA report "Inspector's Log for Controlled Substances" [PSD PRINT INSPECTOR LOG]. This report lists all active orders for controlled substances issued to an authorized storage location (e.g., research section) by pharmacy.

(3) Use the Inspector's Log for Controlled Substances to identify the controlled substances the authorized location should have presently. Each drug on the report should be accounted for. The inventory balance will be on VA Form 10-2638, or subsequent issue.

(4) Initial each entry on the Inspector's Log for Controlled Substances and note by the entry if a drug was not found, VA Form 10-2638 was not found, or the count did not match the balance on VA Form 10-2638. This log should be included in the report to the CSC.

(5) If an automated dispensing device is used to store the controlled substances, perform the physical inventory using the inventory functionality of the ADC and not the "Inspector's Log for Controlled Substances."

c. In the inpatient or clinic setting, the CSI must verify there is a hard copy order (electronic or written) in the patient's medical record, there is documentation of administration, and documentation of 2 signatures for any wasting of partial doses for five randomly selected dispensing activities. If there are less than five dispensing activities for the previous 30 days, all orders must be reviewed.

(1) For controlled substance storage areas with more than one ADC, the requirement is to review five orders for each ADC to a maximum of 20 orders. **NOTE:** *For example, if the Operating Suite has 3 ADCs, 15 dispensing activities should be reviewed, five from each ADC. However, if the Operating Suite has 10 ADCs, 20 dispensing activities should be reviewed. In addition, the 20 dispensing activities should include at least 1 from each ADC.*

(2) The dispensing activities should be randomly chosen from the appropriate ADC transaction report.

(3) For controlled substance storage areas that do not have ADCs, the five dispensing activities should be randomly chosen from the entries on VA Form 10-2638, "Controlled Substance Administration Record."

d. The CSI must verify staff inventories are completed if required in local policy. **NOTE:** *There are no requirements in national policy for unit/clinic staff to perform inventories outside of the inspection program. However, if local policy requires staff to complete inventories at designated time frames (e.g., daily, weekly, change of shift, etc.) then the CSI should verify all the required inventories were completed.*

7. PROCEDURES FOR INSPECTION OF RESEARCH LABORATORIES

a. The researcher or designated point of contact must be present during the inventory and inspection of the controlled substances.

b. The CSI must perform a complete (100%) physical inventory count every month:

(1) For research areas that do not store controlled substances in an ADC, the CSI should print, or obtain from the CSC or pharmacy liaison, a copy of the VistA report "Inspector's Log for Controlled Substances" [PSD PRINT INSPECTOR LOG] for each research area. This report lists all active orders of controlled substances issued to the research section by pharmacy. **NOTE:** *If a research area uses an automated dispensing device to store controlled substances this report is not used.*

(2) The CSI must use the Inspector's Log for Controlled Substances to identify the controlled substances the research area should have present. Each drug on the report should be present in research with a corresponding VA Form 10-2638. The inventory balance will be on VA Form 10-2638.

(3) The CSI must initial each entry on the "Inspector's Log for Controlled Substances" and note by the entry if a drug was not found, VA Form 10-2638 was not found, or the count did not match the balance on VA Form 10-2638. This log should be included in the report to the CSC.

(4) The CSI should list any drug present that is NOT on the Inspector's Log for Controlled Substances, or in the ADC, as a discrepancy. This may indicate research did not obtain the medication from pharmacy as required in VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), or subsequent policy issue.

(5) Ensure that when inventory for a specific VA Form 10-2638 is depleted, the form is zeroed out, signed, and dated by the researcher. **NOTE:** *Once zeroed out, the completed form must be returned to pharmacy service within the time frame requirements defined in VHA Handbook 1108.01, pharmacy stock or its successor. Any lapses with regard to this requirement are to be noted on the inspection worksheet.*

(6) If an automated dispensing device is used to store the controlled substances in research, the physical inventory is performed using the inventory functionality of the automated dispensing device and not the Inspector's Log for Controlled Substances report.

(7) For pharmacies dispensing from a Class II safe, the "Patient Specific Controlled Drug Administration Record" may be used in lieu of VA Form 10-2638 and the "Outstanding Transactions Report" may be used in lieu of "Inspector's Log for Controlled Substances".

c. Inspectors are cautioned not to open sealed boxes unless evidence of tampering is encountered. **NOTE:** *Sterile solutions or powders custom packaged or repackaged*

for research use must not be adulterated or rendered non-sterile by auditing procedures.

(1) The need for special precautions must not prevent an accurate audit. An audit method that allows compliance, while protecting the CSI and the integrity of powders or liquids, is to be developed, with the input of the Chief of Pharmacy, Associate Chief of Staff for Research and Development (or equivalent), research investigators, and veterinarian (if applicable) as needed. **NOTE:** *The use of small, pre-measured, and sealed aliquots of powder or liquid (versus bulk storage) can allow ready measurements while maintaining sterility and preventing needless repetitive weighing or volume measurements.*

(2) On rare occasions a powder, liquid, or injectable, if improperly handled, could represent a potential health risk to inspectors. In such cases, the principal investigator or designee must ensure that appropriate handling precautions are clearly communicated on the item (e.g., if the controlled substance could be absorbed by skin contact, an appropriate warning should be present on the container to avoid skin contact or to only open the item in a chemical hood or other suitable containment environment). Inspectors must not hesitate to ask research personnel, with more appropriate training, to handle items in such circumstances.

(3) In some cases it may be necessary to estimate the quantity rather than risk contamination, loss of drug or safety. An example would be open multi-dose injectable vials. It is recommended the CSI, in collaboration with the research staff person, determine if the amount in the vial is approximately the amount listed on the inventory sheet. The vial should only be entered and contents withdrawn if there appears to be a significant different between the two (e.g., the inventory record indicates there should be 12ml in the vial, however it appears there is 1-2 ml in the vial).

8. PROCEDURES FOR INSPECTION OF THE CONSOLIDATED MAIL ORDER PHARMACY

a. The Program Manager or Clinical Pharmacist Specialist for Controlled Substances (CSPS) or designee must be present during the monthly inspections.

b. The CSPS or designee and CSI must perform a complete physical count during 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. **NOTE:** *Liquids are dispensed in sealed containers, therefore counted as units and not measured.*

(1) The CSI must note the counts on the inventory sheet of each drug counted and sign and date the last page. The inventory sheet must be included in the report to the CSC.

(2) Do not open manufacturer sealed packages to verify inventory. **NOTE:** *The CSI is not to open any manufactured sealed packages of controlled substances for actual count, unless there appears to be evidence of tampering. The CSI must open and count contents of partial bottles that have been re-sealed by pharmacy. The CSI may*

not use the hand-written count of contents noted by pharmacy on the bottle as confirmation of the inventory count.

c. The CSI must ensure that any drug removed from inventory for destruction is secured and documented in the CMOP software.

(1) The CSPA, or designee, generates the Destruction Holding Report from the CMOP software which lists all drugs waiting turn over to reverse distributor or local destruction.

(2) The CSI must verify there is a corresponding sealed evidence bag containing drug for each line item listed on the report.

(3) The sealed evidence bags should not be opened or contents counted unless there are signs of tampering.

d. The CSI must conduct an audit trail of 10 items turned over to the reverse distributor for destruction. The CSI should randomly choose 10 items from the prior Destruction Holding Report turn over to the reverse distributor and ensure those 10 items are on the receipt provided by the reverse distributor.

e. The CSI must verify and document, on the Pharmacy Controlled Substance Inspection Report, that inventories have been completed as required in VHA Handbook 1108.01, Controlled Substances (Pharmacy Stock), or subsequent policy issue, or local policy if such is more stringent than the requirements of this Handbook) for the prior month. The CSI should visually review the electronic record of perpetual inventory validation.

9. TOOLS FOR DETECTING DIVERSION

The CSC and Pharmacy designee may expand the scope of the monthly inspections by utilizing the Controlled Substances Monitoring menu in VistA, ADU reports and/or vendor software (e.g., Pandora) to identify potential problem areas.

10. REPORTING UNRESOLVED DISCREPANCY OR LOSS OF CONTROLLED SUBSTANCES

Reports of significant loss, diversion or potential diversion should be reported according to the requirements in VHA Handbook 1108.01, or subsequent policy issue.

**EXAMPLES OF DISCREPANCIES AND CONTROLLED SUBSTANCE
VULNERABILITIES**

This list of examples was developed to assist CSCs in training inspectors and developing worksheets that will help ensure accurate capture and reporting of discrepancies and vulnerabilities. The list is not all inclusive, and facilities may have additional tools such as third party software or ADC reports that are used to capture and trend information. The CSC is not expected to track and trend every example given. The CSC should focus on examples that are repetitive inspection findings and present challenges within their facility.

A. Discrepancy Examples Include:

(1) When the inventory count does not match the inventory print sheet, the expected inventory on VA Form 10-2638, or the expected inventory in the ADC.

(2) During order review, the CSI cannot find: a provider order; documentation of administration; or documentation of waste (if partial dose administered) in either the medical record or paper flow sheets.

(3) Any item on the VistA report that does not appear on the ADC report, or any item on the ADC report that does not appear on the VistA report, when performing the 1 day reconciliation process for ADCs.

(4) When the prescription pads count does NOT match the recorded inventory number.

(5) When the lock number on the cache container does NOT match the lock number of record, as recorded by pharmacy.

(6) Holding numbers on the Destruction Report that does NOT have a corresponding bag with drugs.

(7) Prescription entry on the non-digitally signed report and NO hard copy prescription to match it.

(8) Information on the hard copy prescription different from information on the non-digitally signed report (patient name, drug name, quantity, strength, provider, number of refills, etc.).

(9) Medication listed on the Inspector's Log for Controlled Substance is not found in the controlled substance storage area.

(10) When a partial dose is given and there is no documentation of waste for the remaining quantity.

B. Controlled Substance Diversion Vulnerability Examples include:

(1) When the required staff inventories were not completed per policy requirements.

(2) When finding controlled substances unsecured on a medication cart or counter.

NOTE: *While the inspector is not required to check every spot for unsecured medication, the inspector should report something like this if s/he sees it.*

(3) A missed inspection or if the CSI is turned away by ward/clinic staff at an inspection area.

(4) Drugs identified for destruction are NOT sealed in an evidence bag.

(5) Drugs that are NOT on the destruction holding report but are; stored in a box, on a shelf, in drawer, etc. and “waiting to be posted to the destruction holding report”.

NOTE: *CSIs should be instructed to question any controlled substances they find, that are NOT counted as part of inventory or destruction review.*

(6) When there is a time difference, between medication removal from ADC and return to ADC (or wasted), of greater than 2 hours. **NOTE:** *Some facilities have a time frame defined in local policy. If the time frame is defined in local policy and is less than 2 hours, the time frame defined in local policy should be used.*

(7) Medication present in research that is NOT on the list provided by pharmacy or included on ADC inventory. **NOTE:** *This would be indicative that the medication was not issued by the VA pharmacy. Policy requires research to obtain all controlled substances from VA Pharmacy Services.*