

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. This revision clarifies the responsibilities of the Controlled Substance Coordinator as they pertain to the monthly inspection process.
- 3. RELATED DIRECTIVE.** VHA Directive 1108 (to be published).
- 4. RESPONSIBLE OFFICE.** The Chief Consultant, Pharmacy Benefits Management Strategic Health Group (119), within the Office of Patient Care Services is responsible for the contents of this Handbook. Questions may be addressed to 202-461-7362.
- 5. RESCISSIONS.** VHA Handbook 1108.02 dated February 1, 2010, is rescinded.
- 6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working day of April 2015.

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CONTENTS

INSPECTION OF CONTROLLED SUBSTANCES

PARAGRAPH	PAGE
1. Purpose	1
2. Definitions and Authority	1
3. Scope	1
4. Responsibilities of the Medical Center Director	1
5. Responsibilities of the Pharmacy Director, CMOP Facilities	2
6. Responsibilities of the Medical Facility Chief of Staff and the Chief Nursing Executive (CNE)	4
7. Responsibilities of the Medical Facility Chief of Pharmacy Services.....	4
8. Responsibilities of the Controlled Substance Coordinator	4
9. Responsibilities of Controlled Substance Inspectors (CSIs)	6
10. Procedures for Inspection of the Pharmacy	6
11. Controlled Substance Drug Destruction	8
12. Procedures for Inspection of Inpatients Units and Clinics	8
13. Procedures for Inspection of Research Laboratories	9
14. Procedures for Inspection of Automated Dispensing Equipment	10
15. Tools for Detecting Diversion	10
16. Documentation of Discrepancy or Loss of Controlled Substances	11

APPENDIXES

A VA Form 10-2320, Schedule II, Schedule III Narcotics and Alcohols Register	A-1
B Sample of VA Form 10-2638, Existing Stock of Controlled Substance Administration Record	B-1
C Sample of VA Form 10-2577F, Security Prescription Form	C-1

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

a. **Controlled Substances.** Controlled substances, subject to inspection, consist of drugs and other substances by whatever official name, common name, usual name, chemical name, or designated brand name, that are listed in Title 21 Code of Federal Regulations (CFR) Schedule I 1308.11, 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.

b. **Designated Provider.** A 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.

c. **Unresolved Discrepancies.** Any variance from the expected inventory that cannot be explained.

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, inpatient units, 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 CENTER DIRECTOR

Each Medical Center Director is responsible for:

- a. Establishing an adequate and comprehensive system for controlled substances to ensure safety and control of all inventories.
- b. Requiring uniform and complete compliance with VHA policies on controlled substances.
- c. Establishing local written medical facility policy(ies) on the 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 employee's position description or functional statement.

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

e. Appointing an adequate number of Controlled Substance Inspectors, in writing, who do not have involvement in drug procurement, prescribing, dispensing, or administration. **NOTE:** *Pharmacists, nurses, or physicians who work in other areas (e.g., Performance Improvement) having no involvement with medication prescribing, dispensing, or administration may be appointed as CSIs.*

f. Providing an orientation for new CSIs and ensuring that CSIs receive annual updates regarding problematic issues identified through external survey findings and other quality control measures. **NOTE:** *It is recommended that this information be provided in an annual meeting; however, email or other means of communication may be used if necessary to ensure that all CSIs receive the information. Documentation of local meetings should be maintained in the Learning Management System (LMS).*

g. Appointing CSIs to a term not to exceed 3 years; there is no term limit for the CSC. **NOTE:** *Due to the importance of the controlled substance inspection program and for ensuring accountability and confidence in the management and use of controlled substances, the Medical Center Director needs to formally express appreciation to CSIs and the CSC as they complete their terms. CSIs may be reappointed after a 1-year hiatus.*

h. Ensuring that the current Veterans Health Information System and Technology Architecture (VistA) controlled substance software packages are utilized in all inpatient and outpatient settings. **NOTE:** *The Pharmacy Automated Data Processing Application Coordinator (AdPac), or other pharmacy appointee, must ensure that all VistA controlled substance packages are utilized and that all appropriate pharmacy staff are trained on its use.*

i. Ensuring that all inspection records are retained for a period of 3 years.

j. Immediately referring to the Office of Inspector General, Office of Investigations, any criminal matters involving felonies related to controlled substances (38 CFR § 1.204).

5. RESPONSIBILITIES OF THE PHARMACY DIRECTOR, CMOP FACILITIES

The Pharmacy Director of a CMOP facility is responsible for:

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

b. Appointing a CSC, responsible for coordination of the inspection program, and an adequate number of CSIs.

(1) The CSC must not have a connection with any component of the controlled substance program, including the procurement, dispensing or record keeping of these medications.

(2) The CSC duties must be included in the employee's position description or functional statement.

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

(4) The CSC must complete appropriate training and the Controlled Substance-Drug Diversion Inspection Certification course available on the VA LMS website at: www.insidelms.va.gov 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 Web site and is not available to the public.* Documentation of Certification is maintained in the LMS.

c. Appointing, in writing, an adequate number of CSIs who do not have involvement in controlled substance procurement, dispensing or record keeping. For example: Pharmacists and technicians never assigned controlled substances responsibilities may be utilized, as well as administrative assistants, secretaries, or medical equipment technicians, etc.

d. Appointing inspectors to a term not exceeding 3 years. There is no term limit for coordinators. **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 and CSC as they complete their terms. Inspectors may be reappointed after a 1-year hiatus.*

e. Providing an orientation for new inspectors and an annual refresher training to furnish annual updates regarding problematic issues identified through external surveys or other quality control measures for the current inspectors. **NOTE:** *It is recommended that this information be provided in an annual meeting; however, email or other means of communication may be used if necessary to ensure that all CSIs receive the information.*

f. Ensuring all controlled substance storage and dispensing areas are inspected on a monthly basis and verifying all inventory stock and record keeping (e.g., procurement, receipt, dispensing, and inventory (active and outdated). **NOTE:** *On a rare occasion a given area may go uninspected. However, this area must be inspected in the subsequent month.*

g. Ensuring that all inspectors complete a local orientation and the on-line Controlled Substance Certification Program (subpar. 5b(4)) prior to participation in the inspection program. **NOTE:** *Documentation of Certification is maintained in the LMS.*

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

6. RESPONSIBILITIES OF THE MEDICAL FACILITY CHIEF OF STAFF AND THE CHIEF NURSING EXECUTIVE

The Chief of Staff (COS) and the Chief Nursing Executive (CNE), or designees, are responsible for:

- a. Ensuring that all requirements for handling, storage, and security of controlled substances under control of clinical services are followed.
- b. Providing access and support for all assigned inspections in clinical services areas of responsibility, without prior notice.

7. RESPONSIBILITIES OF THE MEDICAL FACILITY CHIEF OF PHARMACY SERVICES

The Chief of Pharmacy Services, or designee, at the local facility is responsible for:

- a. Ensuring that all requirements in VHA Handbook 1108.1 are followed and that all the necessary information is available to CSIs.
- b. Ensuring that responsibility for balance adjustments in the Controlled Substances VistA Package and automated dispensing devices within the pharmacy is assigned to as few pharmacy staff as possible.
- c. Being present during monthly inspections of the facility pharmacies and performing a complete physical count, as necessary.
- d. Reviewing, monthly, all controlled substance balance adjustments, and reporting any unresolved discrepancy to the CSC. **NOTE:** *The reviewer cannot perform inventory balance adjustments at any time.*

8. RESPONSIBILITIES OF THE CONTROLLED SUBSTANCE COORDINATOR

The CSC is responsible for ensuring that:

- a. The required inspections are completed in each area that stores controlled substances each month. **NOTE:** *On a rare occasion a given area may go uninspected. However, this area must be inspected in the subsequent month.*
- b. All new CSIs complete the Controlled Substance-Drug Diversion Inspection Certification course available on the LMS prior to participation in the inspection program. Documentation of Certification will be maintained in the LMS. **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 web site and is unavailable to the public.*

c. All local orientation and initial certification training provided is documented in the LMS. Competency assessments of the CSIs are documented annually. Attendance at annual refresher meetings is documented in the LMS. All annual updates sent to the CSIs are maintained on file.

d. Inspectors conduct monthly, unannounced controlled substance inspections of the Pharmacy's vault(s) inpatient and outpatient working stocks, all units, research, emergency carts, pharmaceutical caches, and CBOCs where controlled substances are stored.

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

f. The inspectors verify source data (e.g., prescriptions, providers orders, Bar Code Medication Administration (BCMA) records, and other manual records) to detect potential diversion.

g. All monthly inspections are assigned and completed. *NOTE: To ensure the element of surprise, inspections must not be scheduled at the same time each month. Inspection dates are to be randomly selected.*

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

i. All documented complaints relating to possible diversion activities (e.g., shorted quantities, mail prescriptions not received, etc.) are recorded by the patient advocate or medical center liaison for the CMOP and summarized for review by either the Medical Center or CMOP Director in the Controlled Substances Monthly Report.

j. All resolved discrepancies, noted during the inspection process, are reported to either the Medical Center or CMOP Director for trending purposes.

k. Unresolved discrepancies are reported to either the Medical Center or CMOP Director for further investigation.

l. A "Quarterly Trends Report" is provided to either the Medical Center or CMOP Director summarizing any identified discrepancies, problematic trends, and potential areas for improvement. For example: discrepancies need to be trended by location, drug, and number of doses.

m. Either the CSC or the pharmacy liaison generates a complete list of the serial numbers for distributed VA Form 10-2638, Controlled Substance Administration Records, by unit, clinic, etc. This list provides all serial numbers to the CSIs for use in the monthly checks of controlled substance inventories and records. *NOTE: The CSIs must have access to: the inactive VA Forms 10-2638, in those rare instances when they are utilized; VA Forms 10-2638, returned to the pharmacy since the last inspection; or the electronic equivalent data in VistA. The records used for the monthly inspection must part of the VistA package, automated dispensing equipment, or both.*

9. RESPONSIBILITIES OF THE CONTROLLED SUBSTANCE INSPECTORS (CSIs)

The CSIs are responsible for:

- a. Conducting any random, unannounced inspections as assigned by the CSC. Each inspection area must be completed on the day it is initiated. **NOTE:** *All CMOP controlled substances inspections are to be completed on the same day. However, at the Medical Center inspections may be assigned on multiple days as long as the element of surprise is maintained.*
- b. Checking on-hand inventories.
- c. Certifying by memorandum, as defined in local policy, to the CSC, the accuracy of the records and inventory of the controlled substance areas that they have inspected.
- d. Randomly verifying that there are valid outpatient prescriptions or inpatient orders for Schedule II prescriptions to support the dispensing activity. **NOTE:** *For the frequency of random verification see VHA Handbook 1108.1.*
- e. 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 inspections. In the case of the CMOPs, the responsible controlled substance pharmacist must be present at the time of inspection.
- b. The physical inventory inspection includes all active stock of Schedule II to V controlled substances (including outdated stock), and related records (VA Form 10-2320, Schedule II, Schedule III Narcotics and Alcohol Register; VA Form 10-2638; and VA Form 10-2577 F, Security Prescription Form; and electronic equivalents).
- c. The Chief of Pharmacy, or designee, and CSI must perform a complete physical count in the pharmacy 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. The CSI must weigh all unsealed powders and measure all unsealed liquids with a volumetric cylinder, unless the container has a graduated scale for volumetric measurement.
- d. The CSI(s) must verify the accuracy of the pharmacy records by dating and initialing VA Form 10-2320, or the electronic equivalent for each drug or preparation, at the time of inspection. This includes:
 - (1) All pharmacy working stocks of controlled substances;
 - (2) A physical count quarterly and monthly verification of the seals of the Emergency Drug Cache;
 - (3) All automated dispensing machines containing controlled substances;

(4) All drugs held for destruction by comparing with the "Destruction File Holding Report;" and

(5) Prescription pads.

e. Do not open manufacturer sealed 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.*

f. The CSI must conduct Inventory Reviews.

(1) The inspecting official must verify and document, 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, unless there is a Federal holiday. On weeks containing a Federal holiday, only two inventories are required in pharmacies open 6 or 7 days per week.

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

(2) VHA All Hazards Cache controlled substance inventory must be reviewed every 72 hours. That portion of the inventory that is contained in a bin with an intact seal does not need to be individually counted, but can be accounted for by verifying that their outer seals are intact. All discrepancies, evidenced by this review process, must be resolved when evidenced. Unresolved discrepancies must be reported by the inspectors as a component of their monthly report. *NOTE: A waiver to perform weekly reviews must be granted by the Office of the Pharmacy Chief Consultant, Pharmacy Benefits Management (PBM) Services.*

(3) The CSI ensures that all controlled substances have been received and placed into inventory by reviewing the monthly prime vendor invoice, detailed purchase invoices, and summary reports from prime vendor or direct purchase invoices against the pharmacy drug receipt history report in VistA. *NOTE: All controlled substance inventories must be first received into VistA prior to issuing to automated equipment.*

g. A CSI must inspect the Outpatient Pharmacy.

(1) In the outpatient pharmacy, the CSI 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 Drug Enforcement Agency (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 "Daily Activity Log" in VistA, 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.

11. CONTROLLED SUBSTANCE DRUG DESTRUCTION

a. Out of date, or other unusable substances that are returned to the pharmacy must be properly stored for transfer to a reverse distributor, or destroyed under the control of pharmacy. The CSI must verify that all drug transfers or destructions are completed at least quarterly, and documented on the inspection report.

b. The CSI must review the audit trail for ten randomly-selected drugs for destruction by comparing the destroyed drugs report to the signed DEA Form 41, Registrants Inventory of Drugs Surrendered; ensuring that accountability is maintained from the time of turn-in to pharmacy until destruction or transfer to a reverse distributor. Any transfer to a reverse distributor must be validated by a signed receipt. Upon transfer the reverse distributor assumes full control and responsibility for the controlled substances.

c. The CSI must ensure that any drug stock removed from inventory for destruction, since the last inspection, is properly documented on the "Destruction File Holding Report."

12. PROCEDURES FOR INSPECTION OF INPATIENT UNITS AND CLINICS

a. The unit or clinic manager, or designee, is to be present during the inventory and inspection of controlled substances.

b. The CSI must perform a complete physical count on all unit and clinic areas during the first month of each quarter. A random physical count of a minimum of 10 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 CSI 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 CSI must:

(1) Validate control substance transfers, to ensure that appropriate documentation as to the transfer is maintained, by reviewing the document trail of any two transfers from one storage area to another. *NOTE: This is only necessary if controlled substance transfers are permitted by local medical center policy.*

(2) Initial and date the inspection worksheet to verify the accuracy of records on the unit or clinic.

(3) Ensure that change of shift counts for non-automated dispensing units and weekly inventories for automated units on all wards and remote storage areas are completed.

NOTE: This is only necessary if shift counts and weekly inventory verifications are required by local medical center policy.

13. PROCEDURES FOR INSPECTION OF RESEARCH LABORATORIES

a. The CSI must validate that the medical center Director has authorized a designated provider to ensure security, handling, and storage of controlled substances in a research laboratory.

b. The designated provider or designee, is to be present during the inventory and inspection of the controlled substances.

c. The CSI must:

(1) Validate that all controlled substances stored in the research laboratory were ordered through and received from Pharmacy Service.

(2) Perform a complete physical count of all controlled substances each month. Manual entries must be reconciled on VA Form 10-2638 for each drug or preparation during the inspection.

(3) Validate that a VA Form 10-2638 accompanies each container of drugs issued. *NOTE: Research staff must always use a printed copy of VA Form 10-2638.*

(4) Ensure that when inventory for a specific VA Form 2638 is depleted that the form is zeroed out, signed, and dated by the designated provider. *NOTE: Once zeroed out, the completed form must be returned to pharmacy service within 72 hours. Any lapses with regard to this requirement are to be noted on the inspection worksheet.*

(5) Initial and date their inspection worksheet to verify the accuracy of all records in the research section. *NOTE: No change of shift counts or daily counts are required of the research department.*

d. Inspectors are cautioned not to open sealed boxes unless evidence of tampering is encountered. 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 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 or liquid, 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.

14. PROCEDURES FOR INSPECTION OF AUTOMATED DISPENSING EQUIPMENT

a. The CSI must have specific, written instructions on how to inspect each automated dispensing device that contains controlled substances.

b. Each CSI must be assigned an individual password that enables access only in the presence of an authorized user.

c. A unit or clinic nurse, or authorized provider in the research section, must accompany the CSI during all inspections.

d. The CSI must:

(1) Perform all physical counts on all unit, clinics, and research areas as required by this Handbook.

(2) Reconcile 1 day's dispensing from the pharmacy to each unit of automated equipment. These are to utilize the pharmacy dispensing reports to automated equipment, validating what was received into inventory.

(3) Verify, in the inpatient or clinic setting, 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.*

(4) Ensure that weekly verification for automated units on all devices and remote storage areas are completed. **NOTE:** *This is only necessary if weekly verification is required by local medical center policy.*

15. TOOLS FOR DETECTING DIVERSION

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

b. 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.*

16. DOCUMENTATION OF DISCREPANCY OR LOSS OF CONTROLLED SUBSTANCES

a. In cases of unresolved discrepancies the CSI must provide a report to the CSC, who must make a report of findings to the appropriate Facility or CMOP Director for action.

b. Reports of loss or potential diversion are to be forwarded to Pharmacy Benefits Management Services using mail group at: VHAPBH Pharmacy Reporting CS Diversion/Loss. In all instances this report is to be sent using e-mail encryption. **NOTE:** *In the case of an identified discrepancy or diversion, the procedures outlined in VHA Handbook 1108.1 are to be followed.*

**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/medical/pdf/vha-10-2320-fill.pdf> **NOTE:** *This is an internal VA link not available to the public.*



10-2320-fill.pdf

**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.



10-2638.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.*

This form must be ordered in paper form the Service and Distribution Center. The Stock number is F05466



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