

MONITORING OF NON-CONTROLLED SUBSTANCE MEDICATION RETURNS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Directive outlines procedures for control and monitoring of non-controlled substance medications held for return and associated credits.

2. SUMMARY OF MAJOR CHANGES: This revised VHA Directive provides updated process and reporting requirements for monitoring of non-controlled substance medication returns; specifically, it:

a. Updates requirements for VA Pharmacies to semi-annually test high value returns to determine the amount of credits received for returned drugs is reasonable.

b. Updates requirements for VA Pharmacies to analyze web based reports regarding medication returned for credit to identify potential improvements that may increase the amount of credit received.

c. Revises responsibility for communicating identified findings to the Deputy Chief Consultant and Associate Chief Consultant, Pharmacy Benefits Management (PBM).

3. RELATED ISSUES: VHA Handbooks 1108.05 and 1108.06.

4. RESPONSIBLE OFFICE: The Chief Consultant, Pharmacy Benefits Management (PBM) Services (10P4P) in the Office of Patient Care Services, is responsible for the content of this Directive. Questions may be addressed to 202-461-7326.

5. RESCISSIONS: VHA Directive 2008-021, dated April 17, 2008 is rescinded.

6. RECERTIFICATION: This VHA Directive is scheduled for recertification on or before the last working day of August 2019.

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1. PURPOSE: This Veterans Health Administration (VHA) Directive outlines procedures for control and monitoring of non-controlled substance medications held for return and associated credits. **AUTHORITY:** 38 U.S.C. 7301(b).

2. BACKGROUND: The U.S. Government Accountability Office (GAO) report, VA Medical Centers, Internal Control over Selected Operating Functions Needs Improvement (GAO-04-755), recommended improved oversight of Veterans Affairs Medical Center (VAMC) operations. Specific findings noted in the report were:

a. Internal control over drugs held for return credit provided no assurance that pharmacies were receiving the proper amount of credits for returned drugs.

b. VAMCs use an honor system for returning drugs to manufacturers for credit, relying on contractors that collected and processed recalled, expired, or deteriorated drugs, and relied on others to determine the amount of credits for returned drugs.

c. Pharmacies and VHA managers perform no analysis of drugs returned for credit.

d. Lack of security makes non-narcotic drugs held for return vulnerable to undetected loss, theft, and/or misuse.

3. POLICY: It is VHA policy that non-controlled substance medications held for return for credit must be secured, tracked, and monitored to reduce the possibility of undetected loss, theft, or misuse, and maximize revenues received through credits.

4. RESPONSIBILITIES:

a. **Deputy Chief Consultant and Associate Chief Consultant, Pharmacy Benefits Management.** The Deputy Chief Consultant and Associate Chief Consultant, Pharmacy Benefits Management (PBM), are responsible for:

(1) Reviewing, biannually, reverse distribution vendor data nationally for unusual reimbursement patterns and to identify potential improvements for revenue recovery.

(2) Communicating identified findings and opportunities for improvement from analytic reviews to Pharmacy Chiefs or Pharmacy Managers, VISN Pharmacist Executives (VPEs), Chief Consultant, and Consolidated Mail Outpatient Pharmacy (CMOP) Directors, as appropriate.

b. **Veterans Integrated Service Network Pharmacist Executive.** The Veterans Integrated Service Network (VISN) Pharmacist Executive (VPE), or the person with similar responsibilities in each VISN, is responsible for:

(1) Collecting and collating the results of analytical reviews from VAMCs in the VISN, if requested by the Pharmacy Benefits Management (PBM) Services.

(2) Communicating pertinent findings to the PBM regarding analytic reviews and opportunities for improvement.

c. **Chief of Pharmacy, Pharmacy Manager or CMOP Director.** The Chief of Pharmacy, the Pharmacy Manager, CMOP Director, or the person with similar responsibilities, in each VAMC and CMOP is responsible for:

(1) Ensuring procedures are established to:

(a) Maintain a running list of non-controlled substance medications held for return for credit in facility pharmacies, as they are removed from current supplies, to compare with contractor-prepared lists of returned drugs.

(b) Secure non-controlled substance medications held for return in facility pharmacies as they are removed from current supplies.

(c) Semi-annually test high value returns to determine whether the amount of credits received for returned drugs is reasonable.

(d) Analyze web based reports regarding drugs returned to manufacturers for credits received to identify potential improvements that may increase the amount of credit received.

(e) Communicate findings of all analytic reviews to the VPE.

(2) Ensuring the physical security of outdated non-controlled substance medications.

(a) Drug products designated for return must be stored in a secure locked area separate from normal inventory.

(b) The returned drugs inventory must be reviewed when unusual access patterns are noted during security reviews.

(c) The effectiveness of existing physical security measures must be monitored in place for medications awaiting return for credit and report discrepancies.

(3) Ensuring inventory tracking of outdated non-controlled substance medications.

(a) Maintain a running list of non-controlled substance medications held for return for credit in facility pharmacies as they are removed from current supplies. **NOTE:** *The contents of opened units or bottles may be estimated.*

(b) Ensuring the Reverse Distribution Vendor prepares a list of drugs that are removed from the pharmacy.

(c) The pharmacy list must be compared to the vendor list and any discrepancies resolved.

(4) Ensuring that each facility monitors credits received for returned medications. In order to maximize credits for returned medications, the Chief of Pharmacy, the Pharmacy Manager, CMOP Director, or designee, must review the vendor reports and:

(a) Reconcile credits received against drugs returned.

- (b) Take corrective action on any identified discrepancy.
- (c) Identify any opportunities for improvements.

5. REFERENCES:

- a. U.S. Government Accountability Office, VA Medical Centers, Internal Control over Selected Operating Functions Needs Improvement, GAO-04-755, July 2004. Available at: <http://www.gao.gov/products/GAO-04-755>.
- b. VHA Handbook 1108.06, Inpatient Pharmacy Services.
- c. VHA Handbook 1108.05, Outpatient Pharmacy Services.
- d. U.S. Government Accountability Office, Standards for Internal Control in the Federal Government, GAO/AIMD-00-21.31, November 1999.