MONITORING OF NON-CONTROLLED SUBSTANCE MEDICATION RETURNS

- **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.
- **2. BACKGROUND:** The General Accounting Office's (GAO) report *VA Medical Centers, Internal Control over Selected Operating Functions Needs Improvement (GAO -04-755)*, recommends improved oversight of medical center operations. Specific findings noted in the report are:
- 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. Medical centers 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 fraud.
- **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 fraud and maximize revenues received through credits.

4. ACTION

- a. Responsibilities of Chief of Pharmacy, Pharmacy Manager or Consolidated Mail Outpatient Pharmacy (CMOP) Director. The Chief of Pharmacy, the Pharmacy Manager, CMOP Director or the person with similar responsibilities, in each Department of Veterans Affairs (VA) medical care facility 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 whether the amount of credits received for returned drugs is correct.
- (d) Analyze information regarding drugs returned to manufacturers to identify potential improvements that may increase the amount of credit received.

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- (e) Communicate findings of all analytic reviews to the Veterans Integrated Service Network (VISN) Formulary Leader.
 - (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) A running list of non-controlled substance medications held for return for credit in facility pharmacies as they are removed from current supplies must be maintained. *NOTE:* The contents of opened units or bottles may be estimated.
- (b) The Reverse Distribution Vendor must prepare a list of drugs removed from the pharmacy.
 - (c) The pharmacy list must be compared to the vendor list and any discrepancies resolved.
- (4) Ensuring the facility monitoring of credits received for returned medications. In order to maximize credits for returned medications, the Pharmacy Chief, 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.
- b. <u>VISN Formulary Leader or Pharmacy Benefits Management (PBM) Manager.</u> The VISN Formulary Leader, PBM Manager, or the person with similar responsibilities, in each VISN is responsible for:
- (1) Collecting and collating the results of analytical reviews from local VISN facilities, if requested by the PBM Services.
- (2) Communicating pertinent findings to the PBM regarding analytic reviews and opportunities for improvement.
- c. <u>Associate Chief Consultant</u>, PBM. The Associate Chief Consultant, PBM is responsible for ensuring procedures are established to:

- (1) Review reverse distribution vendor data nationally.
- (2) Communicate findings and identified opportunities for improvement.
- d. **Deputy Chief Consultant, PBM.** The Deputy Chief Consultant, PBM is 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 Formulary Leaders, PBM Managers, and CMOP Directors, as appropriate.

5. REFERENCES

- a. U.S. General Accounting Office, VA Medical Centers, Internal Control over Selected Operating Functions Needs Improvement, GAO-04-755, July 2004.
 - b. VHA Handbook 1108.6, Inpatient Pharmacy Services.
- c. U.S. General Accounting Office, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.31.
- **6. FOLLOW-UP RESPONSIBILITY:** The Chief Consultant, PBM Services (119) in the Office of Patient Care Services, is responsible for the content of this Directive. Questions may be addressed to 202-461-7326.
- **7. RESCISSIONS:** None. This VHA Directive will expire April 30, 2013.

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