

MONITORING OF EXPIRED OR SOON-TO-EXPIRE MEDICATION RETURNS

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

2. SUMMARY OF MAJOR CHANGES: Due to the newly awarded reverse distribution contract, this directive now applies to all expired or soon-to-expire drugs, including controlled substances.

3. RELATED ISSUES: VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017, VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019, and VHA Handbook 1108.05, Outpatient Pharmacy Services, dated June 16, 2016.

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 RESCISSIONS: VHA Directive 1087, Monitoring of Non-Controlled Substance Medication Returns, dated August 13, 2014, is rescinded.

6. RECERTIFICATION: This VHA directive is due to be recertified on or before the last working day of August 31, 2024. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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MONITORING OF EXPIRED OR SOON TO EXPIRE MEDICATION RETURNS

1. PURPOSE

This Veterans Health Administration (VHA) directive outlines standards for the control and monitoring of expired or soon-to-expire medications held for return and associated credits. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

The United States (U.S.) Government Accountability Office (GAO) report, Veterans Affairs (VA) Medical Centers, Internal Control over Selected Operating Functions Needs Improvement (GAO-04-755), recommended improved oversight of VA medical facility 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. VA medical facilities 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. DEFINITIONS

a. **Associated Credits or Return Credits.** Associated credits or return credits are reimbursement from a drug manufacturer to VA for a portion of the value of an expired medication as defined by the individual manufacturer's policy on credits. These credits are issued through the contracted Reverse Distributer to the Pharmaceutical Prime Vendor and can be applied to future drug purchases.

b. **Consolidated Mail Outpatient Pharmacy.** The Consolidated Mail Outpatient Pharmacy (CMOP) uses highly automated facilities to fill prescriptions for Veterans, delivered by mail. VA currently operates CMOP program at seven locations, serving the entire U.S.

c. **Pharmaceutical Prime Vendor.** The Pharmaceutical Prime Vendor (PPV) provides VA and other participating agencies an efficient and economical method of ordering a broad range of pharmaceutical products. The PPV contract is a supply distribution contract with a wholesaler that provides for the daily order placement and daily delivery of pharmaceutical products.

d. **Reverse Distribution.** Reverse distribution is a service that provides collection of damaged, expired, or unsold goods by an authorized vendor. The authorized vendor then sorts the items and returns to the drug manufacturer for credit to the purchasing VA medical facility when appropriate as per manufacturer policy.

4. POLICY

It is VHA policy that expired or soon-to-expire medications held in VA medical facilities for return for credit must be secured and monitored through the time of pick up by the contracted reverse distributor to reduce the possibility of undetected loss, theft, or misuse, and to maximize revenues received through credits.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Ensuring that each VISN Director has sufficient resources to implement this directive in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards and applicable regulations.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for ensuring overall compliance with this directive.

d. **Deputy Chief Consultant for Formulary Management, Pharmacy Benefits Management.** The Deputy Chief Consultant for Formulary Management, Pharmacy Benefits Management (PBM), is responsible for:

(1) Reviewing the data two times per year that is provided via the electronic system supplied by the contracted reverse distribution vendor as per the terms of the contract, 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 Chief Consultant, PBM and VISN Pharmacist Executives (VPEs) during quarterly VPE meetings at a minimum of two times per year, or more frequently if an issue is detected. These presentations can further be shared with Chief of Pharmacy or Pharmacy Managers, CMOP Directors, or other appropriate individuals

during monthly national conference calls if needed as determined with the Chief Consultant, PBM and VPEs.

e. **Veterans Integrated Service Network Director.** The VISN Director is responsible for implementing this directive in all VA medical facilities within the responsible VISN.

f. **Veterans Integrated Service Network Pharmacist Executive.** The VISN VPE, or designee is responsible for:

(1) Collecting and collating the results of analytical reviews, conducted by the VA medical facility Chief of Pharmacy related to credits received through reverse distribution services, or other information that is contained in the electronic system supplied by the contracted reverse distribution vendor (per the terms of the contract from VA medical facilities in the VISN), if requested by the Deputy Chief Consultant for Formulary Management, PBM.

(2) Communicating pertinent findings to the PBM Deputy Chief Consultant regarding analytic reviews and opportunities for increasing the amount of credit received through the reverse distribution process.

g. **VA Medical Facility Chief of Pharmacy, Pharmacy Manager or Consolidated Mail Outpatient Pharmacy Director.** The Chief of Pharmacy, the Pharmacy Manager, CMOP Director, or designee is responsible for:

(1) Ensuring the physical security of expired or soon-to-expire medications in each VA medical facility and CMOP in accordance with VHA Directive 1108.07, Pharmacy General Requirements, dated March 10, 2017, including:

(a) Drug products designated for reverse distribution must be stored in a secure locked area separate from normal inventory (i.e., locked cabinet with limited access to key, controlled substance vault).

(b) Reviewing the expired or soon-to-expire drug inventory when unusual access patterns are noted during security reviews conducted by the Chief of Pharmacy. Examples of unusual access patterns would be employees frequently asking for locked cabinets/drawers to be opened or frequent trips in and out of the controlled substance vault with no clear business need. In the event that discrepancies in expired or soon-to-expire drug inventory are noted, the Chief of Pharmacy should determine whether changes in existing security controls are warranted.

(c) Expired or soon-to-be-expired medications that are controlled substances must be stored and monitored in accordance with VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.

(2) Ensuring inventory tracking of outdated non-controlled substance medications:

(a) Maintaining a running list of non-controlled substance medications held for return for credit in VA medical facility pharmacies as they are removed from current supplies. At a minimum this list must contain drug name and quantity. **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 VA medical facility pharmacy for inventory tracking purposes. At a minimum this list must include the drug name and quantity.

(c) Comparing the VA medical facility pharmacy list to the vendor list and resolving any discrepancies prior to the medications being removed from the VA medical facility by the contracted reverse distributor.

(d) Disposition and accounting of expired or soon-to-be-expired medications that are controlled substances should be accounted for as outlined in VHA Directive 1108.01.

(3) Ensuring that each VA medical facility monitors credits received for returned medications. In order to maximize credits for returned medications, reviewing the electronic system supplied by the contracted reverse distribution vendor as per the terms of the contract to:

(a) Reconcile credits received against drugs returned using both the electronic system supplied by the contracted reverse distribution vendor available PPV credit data. The electronic system supplied by the contracted reverse distribution vendor will catalog the quantity of drugs returned for each associated job number as well as the amount of credit to be received from the manufacturer. The PPV electronic system can be used to determine if the actual credited dollar amount that was supposed to be received for each associated job number was received by the VA medical facility.

(b) If the credits due to the VA medical facility as indicated by the electronic system supplied by the reverse distributor do not match the credits received by through the PPV, the Chief of Pharmacy will work with both vendors to determine why the discrepancy occurred and assure that the VA medical facility receives all credits that were due.

(4) Reviewing at least twice a year VA medical facility returns for drugs with known high acquisition costs to determine whether the amount of credits received for returned drugs is reasonable based on manufacturer policy.

(5) Analyzing the electronic system supplied by the contracted reverse distribution vendor as per the terms of the contract regarding drugs returned to manufacturers for credits received to identify potential improvements that may increase the amount of credit received. Sites may look for trends in items frequently returned that do not receive credit, reasons that items did not receive credit, items that are returned on a recurring basis for credit, or at other aspects of returns based on the data available in the electronic system supplied by the contract reverse distribution vendor as per the terms of the contract and use this information to help improve inventory management practices.

(6) Communicating findings of all analytic reviews outlined in paragraph 5.g.(5) above to the VISN VPE.

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. 38 U.S.C. 7301(b).
- b. VHA Directive 1108.06, Inpatient Pharmacy Services, dated February 8, 2017.
- c. VHA Directive 1108.07, Pharmacy General Requirements, dated March 10, 2017.
- d. VHA Directive 1108.01, Controlled Substances Management, dated May 1, 2019.
- e. VHA Handbook 1108.05, Outpatient Pharmacy Services, dated June 16, 2016.
- f. Department of Veterans Affairs Office of the Inspector General, Audit of Veterans Health Administration's Management of Non-controlled Drugs, dated June 23, 2009. <https://www.va.gov/oig/52/reports/2009/VAOIG-08-01322-114.pdf>.
- g. United States Government Accountability Office, Standards for Internal Control in the Federal Government, GAO/AIMD-00-21.31, dated November 1999. <https://www.gao.gov/assets/80/76455.pdf>.
- h. United States Government Accountability Office, VA Health Care, Pharmacy Inventory Management Could Benefit from System-Wide Oversight, dated September 2018. <https://www.gao.gov/assets/700/694792.pdf>.
- i. United States Government Accountability Office, VA Medical Centers, Internal Control over Selected Operating Functions Needs Improvement, dated July 2004. <http://www.gao.gov/products/GAO-04-755>.