
June 17, 2004



Health Care

DoD Management of Pharmaceutical
Inventory and Processing of
Returned Pharmaceuticals
(D-2004-087)

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Acronyms

CHCS	Composite Health Care System
DMLSS	Defense Medical Logistics Standard Support
DSCP	Defense Supply Center Philadelphia
DVA	Department of Veterans Affairs
ERV	Estimated Return Value
FIFO	First-In, First-Out
GAO	General Accounting Office
GRx	Guaranteed Returns
MTF	Military Treatment Facility
PRMP	Pharmaceutical Returns Management Program
RxCOTS	Pharmacy Commercial Off-the-Shelf
TMA	TRICARE Management Activity



INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-4704

June 17, 2004

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE
(HEALTH AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (FINANCIAL
MANAGEMENT AND COMPTROLLER)
DIRECTOR, DEFENSE LOGISTICS AGENCY
NAVAL INSPECTOR GENERAL
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Report on DoD Management of Pharmaceutical Inventory and Processing of
Returned Pharmaceuticals (Report No. D-2004-087)

We are providing this report for review and comment. The Assistant Secretary of Defense (Health Affairs) did not respond to the draft report. We received comments from the Defense Logistics Agency, the Army, the Navy, and the Air Force. We considered their comments when preparing the final report.

DoD Directive 7650.3 requires that all recommendations be resolved promptly. Defense Logistics Agency comments were fully responsive and no further comments are required. Army, Navy, and Air Force comments were partially responsive. We request that the Assistant Secretary of Defense (Health Affairs) provide comments on Recommendations A.1., A.2., B.4., and B.5.; the Army provide additional comments on Recommendations B.3. and B.5.; the Navy provide comments on Recommendations A.1., B.1., B.3., and B.5.; and the Air Force provide additional comments on Recommendations B.3. and B.5. Comments should be provided by August 16, 2004.

If possible, please send management comments in electronic format (Adobe Acrobat file only) to AudLS@dodig.osd.mil. Copies of the management comments must contain the actual signature of the authorizing official. We cannot accept the / Signed / symbol in place of the actual signature. If you arrange to send classified comments electronically, they must be sent over the SECRET Internet Protocol Router Network (SIPRNET).

We appreciate the courtesies extended to the staff. Questions should be directed to Mr. Michael A. Joseph at (757) 872-4815, ext. 223, or Mr. Robert T. Briggs at (703) 604-8872 (DSN 664-8872). See Appendix I for the report distribution. The team members are listed inside the back cover.

By direction of the Deputy Inspector General for Auditing:

A handwritten signature in black ink that reads "Shelton Young".

Shelton R. Young
Assistant Inspector General
for Readiness and Logistics Support

Office of the Inspector General of the Department of Defense

Report No. D-2004-087

June 17, 2004

(Project No. D2003LF-0109)

DoD Management of Pharmaceutical Inventory and Processing of Returned Pharmaceuticals

Executive Summary

Who Should Read This Report and Why? Hospital administrators, pharmacy managers, and managers of systems supporting DoD pharmacy programs will be interested in this report. The report provides information regarding the need for the appropriate tools to manage pharmacy inventory and process expired pharmaceuticals.

Background. In FY 2003, almost 53 million prescriptions were dispensed at DoD pharmacies, accounting for approximately \$1.7 billion of the \$4 billion in DoD pharmaceutical expenditures. Management of pharmacy matters is assigned to the Director, DoD Pharmacy Programs, who serves as the senior policy adviser to the Assistant Secretary of Defense (Health Affairs) and to the Director, TRICARE Management Activity. DoD established a formal pharmacy supply process in 1992 for DoD pharmacies to order and receive pharmaceuticals directly from wholesalers, known as prime vendors. The prime vendor is a distributor of brand-specific pharmaceutical supplies who provides next-day delivery of those supplies, allowing military treatment facilities (MTFs) to employ a “just-in-time” inventory method.

Many pharmaceutical manufacturers allow pharmacies to return pharmaceuticals if not dispensed before their expiration date. The Defense Supply Center Philadelphia awarded a joint DoD/Department of Veterans Affairs contract, known as the Pharmaceutical Returns Management Program (PRMP), to assist DoD pharmacies in achieving maximum credit for outdated, expired, or recalled pharmaceuticals and to minimize regulatory risk. The amount of credits received by DoD pharmacies each year is not known; however, according to a former PRMP contracting officer, the industry standard is about 2 percent.

Results. Although DoD is working to improve pharmaceutical operations through the acquisition of a comprehensive automated pharmacy system, the chance of dispensing expired pharmaceuticals can be lessened by reducing inventory levels through improvements in policy, oversight, and automation. The comprehensive system will ultimately reduce some, but not all, of the variations in pharmaceutical inventory management processes and procedures within DoD; however, the system is not projected to be operational until FY 2008. DoD needs to establish procedures that will correct the variations in inventory management procedures, as identified at the nine MTFs visited. Specifically, the number of days’ stock on-hand differed among MTFs visited and the variations did not relate to the facilities’ workload. In addition, pharmaceuticals with the shortest shelf life were not always dispensed first and expired pharmaceuticals were not identified or removed in a consistent manner. The Office of the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Departments, needs to develop policies and establish oversight procedures to ensure proper stock levels are

established and maintained, stock rotation is performed, and expiring pharmaceuticals are consistently identified and removed from inventory. In addition, DoD should continue its efforts to implement an automated pharmacy inventory capability, from dispensing through restocking (finding A).

Although DoD has a national contract for processing the return of outdated, expired, and recalled pharmaceuticals and has established a working group to address contract issues, implementing and managing the pharmaceutical returns program needs to be improved. The PRMP contractor did not perform all the services required by its contract. In addition, the two MTFs visited that chose not to use the PRMP contractor did not have a legal contract with the pharmaceutical returns company servicing them. Further, a pharmaceutical prime vendor was paying some pharmaceutical returns companies from MTF credit accounts when it did not have contractual authority to make such payments. Additionally, 14 MTF pharmacies made payments in FY 2003 to pharmaceutical returns companies through potentially improper split payments using Government purchase cards. MTFs also did not inventory expired pharmaceuticals being returned for credit, track the credits associated with the returned pharmaceuticals, or analyze returns data for trends to assist in inventory management. DoD needs to develop policy and establish oversight procedures of its pharmaceutical returns program to have better control over funds expended for the returns services and the credits received, and to reduce the number of pharmaceuticals that will ultimately expire and have to be returned (finding B).

Recommendations in this report, if implemented, should correct the material management control weakness identified. See the Findings section for the detailed recommendations.

Management Comments and Audit Response. The Defense Logistics Agency concurred with the finding and recommendations and noted that the Military Departments, not Defense Supply Center Philadelphia (Supply Center), are responsible for program management of the pharmaceutical returns program. The Supply Center's oversight responsibility is limited to the PRMP contractor. The Defense Logistics Agency further stated that the Supply Center has modified existing pharmaceutical prime vendor contracts and initiated procedures to verify that MTFs have a valid contract with their pharmaceutical returns companies before authorizing use of the prime vendor credit accounts for reimbursement. The Supply Center will also oversee the performance of the PRMP contractor. The Army and the Air Force concurred with most of the recommendations. The Army stated that it is developing a corporate process for improvements to all aspects of pharmaceutical inventory management and revising its primary pharmacy management regulation to include a significantly detailed section on pharmaceutical inventory management. Also, Army Medical Logistics and Air Force Medical Logistics will assist pharmacies in the transition from service agreements to contracts for pharmaceutical returns services. The Army and the Air Force have also assigned pharmacists to a joint working group that is developing requirements for new pharmaceutical returns contracts, including mandatory vendor reports and guidance on the use of those reports. The Navy concurred with the recommendations but did not provide details on how it would implement them. See the Findings sections of the report for a discussion of the management comments and the Management Comments section of the report for the complete text of the comments.

The Defense Logistics Agency comments were fully responsive. The Military Department comments were partially responsive. We request that the Assistant Secretary of Defense (Health Affairs) provide comments and that the Army, the Navy, and the Air Force provide additional comments in response to the final report, as indicated in the transmittal memorandum, by August 16, 2004.

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Background

DoD Pharmacy Program. In FY 2003, there were 587 DoD pharmacies located on 281 Army, Navy, Air Force, and Air National Guard installations. The pharmacies were staffed by approximately 1,200 pharmacists (military, DoD civilian, or contractor) that were supported by approximately 2,800 enlisted pharmacy technicians and other DoD civilian personnel. In FY 2003, almost 53 million prescriptions were dispensed at those DoD pharmacies, accounting for approximately \$1.7 billion of the \$4 billion in DoD pharmaceutical expenditures.

Pharmacy Program Management. The Director, DoD Pharmacy Programs serves as the senior policy adviser to the Assistant Secretary of Defense (Health Affairs) and to the Director, TRICARE Management Activity (TMA) for all DoD pharmacy matters. In addition, the Director, DoD Pharmacy Programs provides oversight for the contracted TRICARE pharmacy programs, such as mail-order pharmacy and retail pharmacy. A pharmacy consultant assigned to each Military Department's Office of the Surgeon General is the chief adviser to the Surgeon General for all pharmacy matters and has managerial oversight of the Military Department's pharmaceutical budget. The consultant is also responsible for monitoring patient safety issues regarding pharmaceuticals. Neither the Director, DoD Pharmacy Programs nor the pharmacy consultants have operational control over individual military treatment facility (MTF) pharmacies.

DoD Pharmacy Boards and Committees. There are four boards or committees that provide guidance regarding DoD pharmacy policy and procedures:

- DoD/DVA Federal Pharmacy Executive Steering Committee
- DoD Pharmacy and Therapeutics Committee
- DoD Pharmacoeconomic Center
- DoD Pharmacy Board of Directors

To promote joint DoD and Department of Veterans Affairs (DVA) initiatives, the first two committees include DVA representation and the third group specifically addresses support of joint DoD/DVA initiatives in its charter. For more information regarding the pharmacy boards and committees, see Appendix C.

Pharmacy Policy. The Office of the Assistant Secretary of Defense (Health Affairs) provides guidance on pharmacy benefits and operations through policy memorandums to the Surgeons General. The Surgeons General establish policies and procedures for the operation of MTFs within their Departments. The primary DoD and Military Department policies addressing pharmacy inventory management are as follows.

- Health Affairs Policy 95-011, "Tri-Service Pharmacy Policy Guidance," July 26, 1995, provides DoD pharmacy policy with the goal of achieving a consistent, equitable, and quality pharmacy benefit within DoD. The policy delineates pharmacy responsibilities for the

MTF commander, the senior pharmacist, and the DoD Pharmacy and Therapeutics Committee.

- Army Regulation 40-3, “Medical, Dental, and Veterinary Care,” November 12, 2002, establishes policies, procedures, and responsibilities pertaining to selected Army Medical Department programs and initiatives, including a chapter addressing pharmacy management. In addition, the Army Medical Command issued Operations Management Bulletin No. 10-02, untitled, September 27, 2002, which provides guidance to Army MTFs for managing and processing expired pharmaceuticals.
- Naval Medicine P-117, “Manual of the Medical Department,” Chapter 21, “Pharmacy Operation and Drug Control,” January 13, 2000, describes procedures for pharmacy operations at naval MTFs, including guidance on pharmacy administration.
- Air Force Instruction 44-102, “Community Health Management,” November 17, 1999, includes guidance on Air Force pharmacy management. In addition, the Air Force issued Air Force Manual 23-110, “Basic United States Air Force Supply Manual,” January 1, 2004. Volume 5 of the Manual, “Air Force Medical Materiel Management System—General” discusses logistical procedures for managing gains and losses of inventory and for handling expired items.

Objectives

Our overall audit objective was to evaluate the effectiveness of the management of pharmaceutical inventory at MTFs. Specifically, we evaluated the maintenance of pharmaceutical inventory, handling of excess and expired pharmaceuticals, the pharmaceutical returns program, and other aspects of managing pharmaceutical inventory. We also evaluated DoD management control programs as they related to the overall objective. See Appendix A for a discussion of the scope and methodology and our review of the management control programs. See Appendix B for prior coverage related to the objectives.

A. Management of Pharmaceutical Inventory

Pharmaceutical inventory management processes and procedures varied within the nine MTFs visited. DoD needs to establish procedures that will correct the variations in inventory management procedures. Specifically, the number of days' stock on-hand was different at the MTFs visited and the variations did not relate to the facilities' workload. In addition, pharmaceuticals with the shortest shelf life were not always dispensed first and expired pharmaceuticals were not identified or removed in a consistent manner. The Office of the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Departments, needs to develop policies and establish oversight procedures to ensure proper stock levels are established and maintained, stock rotation is performed, and expiring pharmaceuticals are consistently identified and removed from inventory. In addition, DoD should continue its efforts to implement an automated pharmacy inventory capability, from dispensing through restocking. With improved policy, oversight, and automation, inventory levels could be decreased and the chance of dispensing expired pharmaceuticals could be lessened.

Pharmacy Supply Process

DoD established a formal pharmacy supply process in 1992 for DoD pharmacies to order and receive pharmaceuticals directly from wholesalers, known as prime vendors. The prime vendor is a distributor of brand-specific pharmaceutical supplies who provides next-day delivery of those supplies. Each MTF uses one of three pharmaceutical prime vendors, depending on the location of the MTF. The pharmaceutical prime vendor program provides the majority of the MTFs' pharmaceutical needs. The balance of pharmaceutical products are provided by and purchased directly from manufacturers in small purchases, normally to alleviate back orders from the prime vendor.

Because prime vendors provide next-day delivery of pharmaceuticals, MTFs can employ a "just-in-time" inventory method. A just-in-time inventory method entails delivery of a commodity when it is needed. The process is used to reduce the inventory levels maintained at the MTFs, eliminating local warehousing of commodities to meet future needs.

Inventory Levels

Pharmaceutical inventory management processes and procedures varied within the nine MTFs visited (three hospitals and six clinics). The number of days' stock on-hand differed among the MTFs and the variations did not relate to the facilities' workload. According to pharmacy personnel, pharmaceutical stock levels were based on factors such as just-in-time ordering, seasonal usage, the

local retiree population, and the need to supply activating reserve units with pharmaceuticals; however, very little validation of the stock levels was performed. At the MTFs visited, the facilities stated that their pharmaceutical stock levels ranged from a 1- to 2-day supply to a 30-day supply.

For the MTFs visited that ordered pharmaceuticals daily, there was no relationship between the facilities' workload and the number of days of stock that personnel stated was maintained on the shelf. For example, the range for the hospitals varied from a 1- to 2-day supply to a 7-day supply, while the range for the clinics was from a 2-day supply to a 10- to 14-day supply.¹ There was also no apparent relationship based on Military Department or the geographic location of the facility.

Only one of the nine MTFs provided documentation that showed the facility was periodically validating that the amount of on-hand stock was equal to the stated days of supply. An employee at the Lawrence Joel Army Health Clinic, Fort McPherson, Georgia, developed a method to validate the number of pills, or other applicable units of measure such as tubes or vials, that constituted the locally established 3-day supply requirement. The method was developed as a part of a graduate study program and the computation was based on usage data from the Composite Health Care System (CHCS). Once the 3-day supply levels were computed for each pharmaceutical, the supply technician determined whether any temporary changes in ordering were needed to bring the supply to the appropriate level. We believe that this method of validating stock levels can make the ordering process more efficient pending deployment of a comprehensive automated pharmacy system that will automatically generate orders for pharmaceuticals based on usage data.

At five of the six clinics, we attempted to validate that the actual stock on-hand was equal to the number of days' stock on-hand that pharmacy personnel stated was maintained. We judgmentally selected five commonly prescribed pharmaceuticals,² counted the amount of stock on-hand for those pharmaceuticals, and requested that the pharmacy provide FY 2003 usage reports from CHCS for those pharmaceuticals. We computed a daily usage rate for each pharmaceutical from the CHCS data and used that usage rate to determine the actual number of days' stock on-hand based on our inventory count. The actual stock on-hand was not equal to the stated stock levels in 54 out of 57 instances, which indicated that MTFs needed to periodically validate the actual stock levels and make ordering adjustments when necessary.

¹The two facilities that stated they maintained a 30-day supply of pharmaceuticals did not order pharmaceuticals on a daily basis.

²Data was collected for each strength stocked for the five pharmaceuticals; however, not all clinics stocked the same strengths for each pharmaceutical. Further, the results are not projectable and do not purport to represent the days' stock on-hand at all DoD pharmacies.

Stock Rotation

Pharmaceuticals with the shortest shelf life were not always dispensed first. According to pharmacy personnel at the MTFs visited, new shipments of pharmaceuticals were stocked behind existing stock to facilitate the first-in, first-out (FIFO) method for dispensing those pharmaceuticals. The use of the FIFO method is to ensure that items with the shortest remaining shelf life are used first.³

We assessed the use of the FIFO method by reviewing the shelf stock at the MTFs visited. Complete shelf reviews were performed at the six clinics visited. We found examples of noncompliance with the FIFO method at all six clinics, ranging from 15 to 50 instances.⁴ See Appendix D for additional information concerning FIFO noncompliance at the six clinics visited. In addition, at one MTF, we observed that personnel were placing newly received pharmaceuticals in front of existing stock.

Identifying Expired Pharmaceuticals

Expired pharmaceuticals were not identified or removed from stock in a consistent manner. At eight of the nine MTFs, we found expired pharmaceuticals on the shelf, either in a position to be dispensed directly from the container to the patient or to be filled from an automated dispensing system. The number of expired pharmaceuticals found in stock ranged from 2 pharmaceuticals at 2 MTFs to 54 pharmaceuticals at 1 MTF, ranging from less than 1 percent to 27 percent of items stocked.⁵ See Appendix D for additional data concerning the number of expired pharmaceuticals identified at the six clinics visited. At two MTFs, the entire shelf stock for certain pharmaceuticals had expired. Expired pharmaceuticals were found in the outpatient and inpatient pharmacies, on the shelves, and in refrigeration units. Specific locations of the expired stock included the front of the shelf, the back of the shelf, and out of direct sight on the top and bottom shelves. The majority of the expired pharmaceuticals had expired in 2003; however, we found five pharmaceuticals with expiration dates prior to 2003.

Pharmaceuticals are approved by the Food and Drug Administration and are assigned an expected life based on studies. When manufactured, the pharmaceutical containers are stamped with an expiration date based on the expected life. The pharmaceuticals should be dispensed in a manner to ensure that the patient does not use the pharmaceutical after the expiration date. Consequently, pharmacies must ensure that the shelf stock is periodically

³At times, the pharmacy receives pharmaceuticals with a shorter remaining shelf life than those in stock.

⁴To determine the number of instances of FIFO noncompliance, we counted each pharmaceutical only once, even though multiple containers of the same pharmaceutical were out of chronological order.

⁵To determine the number of pharmaceuticals expired at each site, we counted each pharmaceutical only once, even though multiple containers of the same pharmaceutical had expired.

reviewed to reduce the chance of dispensing an expired pharmaceutical. The pharmacy must take into consideration the amount of pharmaceutical that is normally dispensed—such as a single dose, a 30-day supply, or a 90-day supply—and remove pharmaceuticals from the shelf accordingly.

At the MTFs visited, the pharmacy staff stated that expired pharmaceuticals were identified and removed from the shelf monthly during manual 100-percent reviews of the shelves. The monthly manual review was necessary because the pharmacies did not have an automated system to monitor the expiration dates. Although the pharmacy staff stated that they conducted monthly reviews, based on our identification of expired pharmaceuticals on the shelves at eight of nine MTFs visited, either the monthly reviews were not being done or the reviews were not completely effective. Of the nine MTFs visited, pharmacy personnel at four MTFs stated that pharmaceuticals were removed from the shelf approximately 30 days before expiration; at two MTFs, pharmaceuticals expiring the current or following month were removed; and at three MTFs, pharmaceuticals were removed 3 months before expiration (to eliminate a problem with dispensing a 90-day supply).

Two MTFs had implemented local methods to alert staff members that certain pharmaceuticals were close to expiration by color-coding the containers. However, during our review of the shelf inventory at both MTFs, we identified problems with the color-coding process. For example, at both MTFs we found pharmaceuticals that should have been color-coded, but were not. In addition, at one MTF, we found pharmaceuticals that should have been removed from the shelf according to their color-coding, but had not been removed. Partial adherence to a system such as color-coding could potentially increase the number of expired pharmaceuticals on the shelf because personnel rely on the pharmaceuticals being correctly color-coded.

We were informed that one Army MTF had an automated process for identifying expired pharmaceuticals. However, our review of that facility showed that the process was not comprehensive. The MTF maintained pharmaceuticals in two sections of the pharmacy—in a warehouse-like storage center and on the shelves for dispensing. The MTF was able to automatically identify expiring and expired pharmaceuticals located in the storage center. However, once the pharmaceuticals were pulled from the storage center and placed on the pharmacy shelves, the MTF had to conduct a monthly manual inspection to remove expiring and expired pharmaceuticals. The multi-level stocking system used was not completely automated, but the majority of the pharmaceuticals were stored in the storage center, which tracked expiration date information electronically. Because fewer pharmaceuticals were on the shelves, less time was required for the manual inspection and the opportunity for overlooking expired pharmaceuticals was decreased. However, because of space and technology requirements, we did not find it a viable option for all MTFs.

Policy and Oversight

The Office of the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Departments, needs to develop policies and establish oversight procedures to ensure proper stock levels are established and maintained, stock rotation is performed, and expiring pharmaceuticals are consistently identified and removed from inventory.

Policy

Office of the Secretary of Defense and Military Department Policies. The Office of the Assistant Secretary of Defense (Health Affairs) had not issued policies that specifically address pharmacy inventory management. In addition, Military Department guidance concerning pharmacy inventory management was limited. None of the Military Department policies include requirements for setting specific stock levels. Army and Air Force policies address stock rotation; however, the policies state only that stocks should be actively managed and rotated to ensure that items with the earliest expiration date are used first. None of the Military Departments' policies contain guidance regarding the identification of expired pharmaceuticals; however, Air Force Manual 23-110 outlines procedures for removal and return of expired items using commercial credit return programs.

MTF Policies. Of the nine MTF pharmacies visited, five (one Army, two Navy, and two Air Force) had local policy addressing specific stock levels, stock rotation, or the identification and removal of expired pharmaceuticals from shelf stock. Only two of the local policies (one Army and one Air Force) address all three issues. Of the two Navy MTF policies, one only addresses stock levels and the other only addresses expiration concerns. The remaining Air Force MTF policy addresses both stock levels and expiration.

The Office of the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Departments, needs to develop policy that standardizes pharmacy inventory management within DoD. In addition, the Military Departments need to develop procedures that implement that policy. Although variations should be allowed based on the facility's workload, mission, and scope and level of care, the policies and procedures should address all aspects of pharmacy inventory management, including stock levels, stock rotation, and uniform procedures for the identification and removal of expired pharmaceuticals. The stock level requirements should take into account just-in-time delivery and require periodic validation of the inventory levels as prescription and patient patterns change. Further, because the most recently received pharmaceuticals may not always have expiration dates later than those currently in stock, the pharmacy staff should periodically reorganize the stock to ensure the pharmaceuticals with the earliest expiration date are dispensed first. In addition, until such time that the process of identifying expired pharmaceuticals is automated, a manual check of stock should be required on a monthly basis so that expired pharmaceuticals will be properly identified and removed. The policy

should clearly outline the time by which pharmaceuticals should be removed; that is, expiring in the current month, the next month, or in 90 days.

Oversight

Oversight of the policies and procedures is also needed to minimize the variations within DoD. For example, although four of the local policies required that expired pharmaceuticals be removed from stock, we found expired pharmaceuticals on the shelves at all four facilities. In addition, the Offices of the Surgeons General and senior pharmacy management need to ensure that the MTFs establish appropriate stock levels and that those stock levels are periodically validated. Oversight is also needed to ensure procedures are established for rotating stock so that the oldest pharmaceuticals are dispensed first. In addition, senior management should verify that the MTFs establish procedures for the consistent identification and removal of expired and expiring pharmaceuticals. Standardized procedures will expedite the transition process when pharmacy staff transfers to a different MTF.

System Integration

DoD should continue its efforts to establish an automated pharmacy inventory capability, from dispensing through restocking. As of February 2004, that capability did not exist. The primary systems that support pharmacy operations and management—CHCS for dispensing and the Defense Medical Logistics Standard Support (DMLSS) system for ordering—do not interface with each other. However, the Office of the Assistant Secretary of Defense (Health Affairs) has begun action to resolve that with the procurement of a comprehensive automated pharmacy system, known as the pharmacy commercial off-the-shelf (RxCOTS) system.

CHCS. CHCS is an automated information system supporting the administration and delivery of health care at MTFs throughout the world. The system includes a pharmacy component, which provides MTF management with pharmaceutical dispensing information, accepts and tracks all patient orders and prescriptions, and provides information for pharmacy-related reports. CHCS has the capability to provide a perpetual inventory of pharmaceuticals; however, it requires the manual entry of the inventory level for each pharmaceutical stocked. Because of the labor-intensive nature of the system, MTF pharmacies have elected to use the system only for the inventory management of controlled pharmaceuticals.

DMLSS System. DMLSS is an integrated system that provides DoD users with medical logistics support, negating the need to stock large inventories. The DMLSS system supports the pharmacy by ordering pharmaceuticals from prime vendors and providing pharmacy management with historical ordering information. However, the DMLSS system does not have the capability to manage pharmaceutical inventory at the pharmacy level or automatically identify ordering requirements. Therefore, the pharmacy technicians examine the shelves to identify pharmaceuticals that need to be replenished and manually identify the

quantity to be ordered. The data is then downloaded into the DMLSS system, which generates an order for submission to the prime vendor.

System Upgrade. CHCS and the DMLSS system do not have the capability to share data that resides in each system. DoD is in the process of upgrading CHCS to CHCS II. The implementation of the upgraded pharmacy portion of CHCS II is planned for FY 2008. The upgrade will include the RxCOTS product that supports total pharmacy processing. RxCOTS includes inventory management capabilities and the ability to perform automated reordering of pharmaceuticals. Although not in the statement of work, TMA staff stated that the RxCOTS software will not replace DMLSS; instead, the RxCOTS functionality will complement the logistics function provided by the DMLSS system, including pharmaceutical ordering, purchasing, and receiving. We believe that when pharmaceuticals' expiration dates can be automatically identified from information embedded in the product labels, RxCOTS should be modified to automatically identify expiring and expired pharmaceuticals. Expiration date identification should be pharmaceutical specific; that is, removal at the 30-day point for some pharmaceuticals and at the 90-day point for most maintenance drugs. Without an expiration date identification process, the system would not provide a total inventory management capability.

Inventory Levels

With improved policy, oversight, and automation, inventory levels could be decreased and the chance of dispensing expired pharmaceuticals could be lessened. However, until such time as the RxCOTS product is implemented, DoD needs to establish interim procedures to support stock level determinations and automated ordering.

The eventual implementation of RxCOTS should facilitate reducing the variations found in stock level determinations. However, the RxCOTS product will not eliminate the need to employ manual procedures to ensure use of the FIFO method of rotating inventory. We believe that the importance of rotating inventory will be less when stock levels are reduced. Stock levels should be maintained that ensure the appropriate amount of pharmaceuticals are available for patients without maintaining excessive supplies that require extra space and extra personnel and could ultimately expire unused. The prime vendor program was established to eliminate the need to overstock supplies.

In addition, more accurate stock level determinations should reduce the magnitude of expired pharmaceuticals remaining on the shelf. With less stock on the shelves, the pharmacy staff removing expired drugs would have less inventory to examine. Further, having an automated process that provides expiration date information would also help identify expiring pharmaceuticals that need to be removed. Because the expiration date is not always checked at the time the prescription is filled, MTFs need to ensure they have minimal amounts of expiring pharmaceuticals in their inventory. Smaller shelf inventories should reduce expiring stock and, therefore, reduce the chance of erroneously dispensing expired pharmaceuticals.

Recommendations, Management Comments, and Audit Response

A.1. We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Department Surgeons General, develop policy and procedures that:

a. Require the military treatment facilities to:

(1) Establish stock levels based on facility workload, scope and level of care, and mission.

(2) Require the facility to validate the stock levels on a periodic basis.

b. Standardize the criteria for identifying expiring pharmaceuticals and removing those pharmaceuticals from inventory.

c. Establish standard procedures for stocking pharmaceuticals on the shelves to ensure those with the earliest expiration date are dispensed first.

d. Establish oversight procedures to ensure the policy and procedures are implemented and followed.

Military Department Comments. The Army concurred and stated that the Army Medical Department is developing a corporate process for improvements to all aspects of pharmaceutical inventory management. The Army is also revising its primary pharmacy management guidance, Chapter 11 to Army Regulation 40-3, which will have a significantly detailed section on pharmaceutical inventory management. The Navy concurred but did not provide additional comments on the recommendation. The Air Force concurred and noted that the Surgeon General's office has been working with the Air Force Audit Agency, DSCP, and the DoD Pharmaceutical Reverse Distribution Working Group to develop criteria for pharmaceutical inventory management. (See page 21 for details about the working group.)

Audit Response. The Army and the Air Force comments were fully responsive, and the Navy comments were partially responsive. Because the Army and the Air Force did not specifically address each element of the recommendation, we will monitor and evaluate their implementation plans to ensure compliance with all elements. We request that the Navy provide comments on how it plans to implement the recommendation. The Assistant Secretary of Defense (Health Affairs) did not provide comments. We request that the Assistant Secretary of Defense (Health Affairs) provide comments in response to the final report.

A.2. We recommend that the Assistant Secretary of Defense (Health Affairs) ensure the upgraded pharmacy component of the Composite Health Care System II:

a. Interfaces with the Defense Medical Logistics Standard Support system for automatic ordering.

b. Incorporates a capability to automatically identify expiring or expired pharmaceuticals, when expiration date information is embedded in pharmaceutical product labels.

Military Department Comments. Although not required to comment, the Army, the Navy, and the Air Force concurred. The Army and the Air Force stated that they support an automated solution for pharmacy inventory control. The Navy stated that DoD is currently evaluating a commercial off-the-shelf pharmacy package for CHCS II and recommended that the Services collectively establish standard business rules to leverage the capabilities of the system.

Audit Response. The Assistant Secretary of Defense (Health Affairs) did not provide comments. We request that the Assistant Secretary provide comments in response to the final report.

B. Pharmaceutical Returns Program

Although DoD has a national contract for processing pharmaceutical returns and has established a working group to address contract issues, improvements are needed in the implementation and management of DoD's pharmaceutical returns program.

- The Pharmaceutical Returns Management Program (PRMP) contractor did not perform all the services required by its contract, and pharmacy staff at three MTFs visited were not aware of all the services available to them in the PRMP contract and had not requested essential services.
- Of the nine MTFs visited, two chose not to use the PRMP contractor. Those two MTFs did not have a legal contract with the pharmaceutical returns company (non-PRMP company) servicing them.
- A pharmaceutical prime vendor was paying at least two non-PRMP companies from MTF credit accounts⁶ when it did not have contractual authority to make such payments.
- Fourteen MTF pharmacies made payments in FY 2003 to a non-PRMP company through potentially improper split payments⁷ using Government purchase cards.⁸
- MTFs did not conduct inventories of expired pharmaceuticals being returned for credit, track the credits associated with the returned pharmaceuticals, or analyze returns data for trends applicable to inventory management.

DoD needs to develop policy and establish oversight procedures to manage its pharmaceutical returns program. With improved policy and oversight, DoD could have better control over DoD funds expended for pharmaceutical returns services and the credits received for returned pharmaceuticals. In addition, MTF management of pharmaceutical inventory would be improved, reducing the number of pharmaceuticals that will ultimately expire and have to be returned.

⁶Credit accounts are maintained by the prime vendors for each DoD customer that receives credits from drug manufacturers for returned drugs.

⁷Split payments are multiple payments made on the same day to the same company, each under the micro-purchase threshold.

⁸We based our analysis of this issue on Government purchase card program data provided by the Defense Manpower Data Center.

Pharmaceutical Returns

Many pharmaceutical manufacturers allow pharmacies to return certain pharmaceuticals if they are not dispensed before their expiration date. Each manufacturer establishes its own conditions for accepting the returned pharmaceuticals. Generally, the manufacturer issues a check, in-kind exchange, or other form of credit to the purchaser upon the return of the expired pharmaceuticals. A former PRMP contracting officer at DSCP, who conducted extensive research of the pharmaceutical returns industry prior to awarding the PRMP contract, stated that the industry standard for returns is approximately 2 percent of the total cost of pharmaceutical expenditures.

MTF pharmacies purchase most of their pharmaceuticals from prime vendors, not directly from manufacturers. Therefore, most refunds for expired pharmaceuticals are issued to the prime vendors, who then assign the refunds to the appropriate credit accounts. To assist pharmacies with the returns process, pharmaceutical returns companies⁹ were established. For a negotiated fee, the returns companies collect the expired pharmaceuticals; return the pharmaceuticals to the manufacturer, as appropriate; dispose of any pharmaceuticals that are not returnable; and, in some cases, provide support in the collection and reconciliation of the credits received. The prime vendors maintain the MTF credit accounts. Generally, the MTFs must use the credits within 90 days.¹⁰

Pharmaceutical Returns Within DoD

Pharmaceutical Returns Companies. DSCP awarded a joint DoD/DVA PRMP contract to Guaranteed Returns (GRx) on January 31, 2001, and administers the contract. The initial contract period was for 15 months, with three additional 15-month option periods. DoD has exercised the second option period, which began on August 1, 2003. The joint contract was awarded to assist DoD and DVA pharmacies in achieving maximum credit for outdated, expired, or recalled pharmaceuticals and to minimize regulatory risk, especially in the area of waste disposal. The contractor processes pharmaceutical returns for DoD and DVA medical facilities within the United States and overseas.¹¹ It is not mandatory that DoD and DVA pharmacies use the contract.

According to GRx staff, it currently has 22,000 customers (or clients) and approximately 60 percent of GRx business comes from hospital pharmacies. DoD and DVA clients are 10 percent to 15 percent of its total client base. DoD clients generate approximately 20 percent of returns processed by GRx in dollar value.

⁹The technical term for pharmaceutical returns companies is “reverse distributors.”

¹⁰If credits are not used within 90 days, the prime vendor generates a check to the U.S. Treasury for the amount of the MTF’s unused credits.

¹¹Pharmaceutical returns from overseas locations cannot include controlled substances.

The other pharmaceutical returns company that has a significant number of DoD clients is EXP Pharmaceutical Services Corporation (EXP). As of October 15, 2003, EXP had 121 DoD accounts at 71 DoD facilities.

The pharmaceutical returns companies visited received payment for their services based on different methods. The PRMP contractor is not paid until the actual credits are received, at which time it is reimbursed based on a percentage of the actual receipts. EXP is reimbursed based on the anticipated return value of pharmaceuticals at the time they are returned.

Credit Information. The Navy and the Air Force received approximately \$9.1 million in credits in FY 2002¹² from the return of expired pharmaceuticals processed by pharmaceutical returns companies. The credits represent approximately 1 percent of FY 2002 pharmacy expenditures. Because information on credits received is not centrally maintained, the Military Department pharmacy consultants collected the information from the MTFs. See Appendix E for additional information concerning pharmacy expenditures and credits received.

Although DoD has a national contract for processing pharmaceutical returns, improvements are needed in the implementation and management of the DoD pharmaceutical returns program.

PRMP Contractor's Relationship With MTFs

The PRMP contractor did not perform all the services required by its contract, and pharmacy staff at three MTFs visited were not aware of all the services available to them in the PRMP contract and had not requested essential services. Seven of the MTFs visited were using the PRMP contractor; none had regularly received all of the reports required by the contract, and two MTFs had not received any reports without requesting them. In addition, three of the seven MTFs were not aware of all of the reports or services available from the contractor.

PRMP Contract. The PRMP contract outlines contractor requirements and responsibilities, including certain specific reporting requirements. The reporting requirements are critical to the management of the pharmaceutical returns process. The reports provide MTF staff with information concerning the actual pharmaceuticals returned, which could be used to identify whether the same pharmaceuticals are being repeatedly returned. The reports also provide information concerning estimated and actual pharmaceutical returns credit, which could be used to determine the cost of the program to the MTF and the amount of credits available for future purchases. See Appendix F for details regarding reporting and other contractor responsibilities.

Returned Goods Reports. The contractor is required to provide the MTF with detailed reports on returned goods, by manufacturer, within 30 days of receiving

¹²Although requested from all the Military Departments for this audit, the Army provided incomplete FY 2002 credits received information.

the returned pharmaceuticals. The reports include the invoice number, product name, national drug code, lot or batch number, quantity, and estimated return value (ERV). Additionally, the contractor is required to list non-returnable items separately on a disposal manifest that includes, at a minimum, the contract number, product name, national drug code or catalog number, quantity, ERV, and reason for non-eligibility for credit. The contractor should provide separate manifests for the disposal of controlled drugs and when disposing of hazardous waste products.

All of the MTFs visited that used the PRMP contractor received some returned goods reports. However, two of the MTFs only received the reports after requesting them from the contractor. A representative from one of the two MTFs stated that she had recently requested and received several reports but had been told by a GRx representative not to expect the reports in the future without an additional charge. Charging for the reports would be in violation of the contract. Another pharmacy representative was not familiar with the contents or availability of the detailed returned goods reports and only received one upon request, after our initial visit.

Monthly Status Report. In addition, the contractor is required to provide the MTF with a monthly status report of credit receipts, listing the manufacturer, ERV, actual return value, and pending credits. None of the MTFs visited reported receiving the required monthly status reports. Also, inventory managers at two MTFs were not aware of the availability or contents of those reports. Both managers expressed a need for manufacturer-specific data, which should be provided in the monthly status report. MTFs reported receiving credit memorandums from their prime vendor and Credit Distribution Notifications from the PRMP contractor. The credit memorandums indicate when credits are posted to the MTF account and the Credit Distribution Notifications show the lump sum credit for the MTF. However, neither document shows outstanding credits by manufacturer. The monthly status reports required by the contract would aid the MTFs in reconciling their credit accounts by identifying which manufacturers still owed them credits. The PRMP contractor stated that because it takes responsibility for reconciling credits for the MTFs, it does not routinely send the monthly status reports to the MTFs, although the status reports are available upon request.

Contracting With Non-PRMP Companies for Pharmaceutical Returns Services

The two MTFs visited that chose not to use the PRMP contractor did not have a legal contract with the pharmaceutical returns company servicing them. Because the PRMP contract is not mandatory, MTFs have the option of selecting a pharmaceutical returns company other than GRx. However, if a different company is selected, the MTF should procure the services in accordance with the Federal Acquisition Regulation.

We visited two MTFs that used a non-PRMP company for pharmaceutical returns services. Both MTFs were using EXP, but neither had a signed contract with

EXP for pharmaceutical returns services. The pharmacy chief at one MTF indicated he had made several requests to EXP for a service contact or agreement, but had not received it. At the other MTF, the returns program manager provided a faxed copy of an unsigned service agreement with EXP for FY 2004, but had no agreement for FY 2003.

EXP management informed us that EXP has several types of contractual arrangements with clients, including blanket purchase agreements, service agreements, and written contracts, depending on the facility serviced. When we explained that the two MTFs we visited receiving EXP services did not have contracts that allowed for either the removal of the expired pharmaceuticals or the payment of those services, EXP management offered no explanation.

Because the pharmaceutical returns services of EXP were being used without a valid contract, we sent a memorandum to the Military Department Surgeons General (Appendix G) requesting that they require MTF commanders to ensure valid authorization was in place for procuring and paying for their pharmaceutical returns services if they were not using the PRMP contractor. Without a valid contract, DoD cannot require pharmaceutical returns companies to provide the services and reports necessary for the MTF to adequately manage its pharmaceutical returns program. The Deputy Surgeon General of the Army provided a prompt response to our memorandum. He informed us that most of the Army MTFs use the PRMP contractor; however, those not using the PRMP contractor would be required to implement local or regional contracts with other pharmaceutical returns companies. In a March 15, 2004, memorandum, the Navy Bureau of Medicine and Surgery stated that use of the PRMP contractor is the preferred source for returns services and that if an alternate source is used, a local contract must be established. The memorandum also forbade the use of Government purchase cards for returns services.

Payment to Non-PRMP Companies

A pharmaceutical prime vendor was paying some pharmaceutical returns companies from MTF credit accounts when they did not have contractual authority to make such payments. In addition, some MTF pharmacies made payments to pharmaceutical returns companies through potentially improper split payments using Government purchase cards.

Payments From Credit Accounts by Prime Vendors. A prime vendor was making payments without any contractual authority to at least two non-PRMP companies for services provided to DoD clients. The prime vendor contracts allow payments from MTF credit accounts only to GRx, the PRMP contractor. However, because it is common practice for prime vendors to make payments from credit accounts to pharmaceutical returns companies in support of all their clients, including private-sector hospitals and pharmacies, the prime vendor continued the practice for DoD clients. According to the prime vendors we contacted, they are receiving verbal approval from DoD clients to make payments on their behalf. However, we could not find authority in the prime vendor

contract to allow for such payments. The two MTFs visited that were not using the PRMP contractor did not have contracts in place to authorize the payments.

Because of the lack of contract authority to pay for pharmaceutical returns services from non-PRMP companies, we sent a memorandum to the Commander, DSCP (Appendix H) requesting that the DSCP staff direct prime vendors to immediately stop payments to non-PRMP companies. In addition, we requested that DSCP direct prime vendors to notify non-PRMP companies that their invoices cannot be paid from MTF credit accounts. We received a response from the Commander, DSCP, who stated that the pharmaceutical prime vendor contracts will be modified to allow for payments from MTF credit accounts to the PRMP contractor or any other pharmaceutical returns company that has a local contract with an MTF.

Payments With Government Purchase Cards. Several MTFs paid for pharmaceutical returns services through potentially improper split payments using Government purchase cards. Our limited analysis of FY 2003 purchase card transactions to one non-PRMP company showed that 14 MTFs had made potentially improper split payments, as defined in section 428, title 41, United States Code. We analyzed 140 purchase card transactions from 30 MTFs. We identified 68 transactions, representing 26 possible split payment episodes, at 14 MTFs—1 Army, 1 Navy, and 12 Air Force. Those 26 episodes totaled almost \$125,000.

We notified the Military Department Surgeons General of the possible payment violations in the same memorandum that we notified them of the contracting problem (see Appendix G). The Deputy Surgeon General of the Army provided a response to our memorandum; however, the response did not specifically address the possible payment violations. In a March 15, 2004 memorandum, the Bureau of Medicine and Surgery forbade the use of Government purchase cards for pharmaceutical returns services.

MTF Management of Pharmaceutical Returns Program

The management of the pharmaceutical returns program needs improvement. The MTFs did not conduct or require on-site inventories of expired pharmaceuticals being returned for credit, did not reconcile credits received for returned pharmaceuticals, and did not analyze returns data for trends to assist in ordering or modifying inventory levels.

On-Site Inventories. The MTFs did not conduct or require on-site inventories of expired pharmaceuticals being returned for credit. Inventories of expired pharmaceuticals prepared before shipment are needed to verify that the pharmaceutical returns company accurately accounts for all returned pharmaceuticals. None of the nine MTFs visited had conducted a complete inventory of expired pharmaceuticals; three had their pharmaceutical returns company conduct an on-site inventory. One of those three MTFs also compiled a list of items as they were being packed for return. However, the list did not contain sufficient detail for comparison with the contractor-prepared inventory.

Two additional MTFs required their pharmacy staffs to prepare turn-in documents when they transferred expired pharmaceuticals to the designated storage area to await return. At one of the MTFs, there were no discrepancies between the contents of seven boxes and their accompanying turn-in documents. At the other MTF, the form that was required for turn-in was completed for only 8 of 59 expired pharmaceuticals. Additionally, only three of the eight forms were correctly prepared. Further, neither of the two MTFs requiring turn-in documents had verified the information or consolidated the information to compile a complete inventory of expired pharmaceuticals. Some pharmacy managers did not see the value of completing on-site inventories of expired, non-controlled pharmaceuticals. A Navy pharmacy chief said doing this would be like having the MTF complete a task that it is paying the contractor to perform. An inventory manager at another Navy MTF said the pharmacy would need additional staff to conduct on-site inventories.

Credit Reconciliation. Most of the MTFs visited did not reconcile the credits they received for expired pharmaceuticals. Only one of the nine MTFs visited attempted to fully reconcile the credits. The MTF pharmacy representatives stated that credit reconciliation was too complex and time-consuming and that they did not receive sufficient documentation from the pharmaceutical returns companies to reconcile the credits with the returns. Full reconciliation is not possible with the reports provided by the pharmaceutical returns companies to the MTFs visited because the reports do not provide sufficient detail on the actual and estimated credits by pharmaceutical and manufacturer. Instead, the MTFs relied on the pharmaceutical returns companies for credit reconciliation.

Although both pharmaceutical returns companies visited provided the MTFs with inventories listing the pharmaceutical ERVs, the companies performed different degrees of credit reconciliation. The PRMP contractor informed us that it performs full credit reconciliation services for its clients. GRx considers the reconciliation service to be a major benefit to MTFs. The company representative noted that because GRx is paid only after the actual credits are received, it is in the company's interest to ensure that as many credits as possible are collected. Conversely, the non-PRMP company, EXP, provides limited credit reconciliation services for its clients. EXP provides the MTF with a summary report that lists the credit anticipated from each manufacturer. The summary report assists the MTF in matching anticipated credits with actual credit memorandums when they are received from the prime vendor. One MTF that attempted to track credits found the summary report beneficial in its reconciliation process.

Trending Expired Pharmaceutical Data. None of the MTFs visited systematically analyzed the returned pharmaceuticals data to assist in modifying ordering or inventory stock levels. A pharmacy manager at one MTF stated that she reviewed the returned goods reports for trends in expiring pharmaceuticals. She said she had not noticed any trends. However, the pharmacy manager was only reviewing a portion of the returned pharmaceuticals information. She only had reports on pharmaceuticals that were returnable; she did not have the disposal manifests for non-returnable pharmaceuticals. We believe a complete analysis of expiring pharmaceuticals requires reviewing data for both returnable and non-returnable pharmaceuticals for an extended period. Other MTF pharmacy managers said they relied mainly on CHCS usage reports for trends. The CHCS

reports are important because they provide the total number of drugs dispensed, but reports on pharmaceutical returns should also be reviewed. Reviewing returned goods reports would help identify repetitive returns that could be alleviated by modifying ordering or inventory stock levels.

The MTFs must take a more active role in the management of their pharmaceutical returns program. The MTFs visited did not routinely review the pharmaceuticals that expired and had to be returned to determine whether they were being ordered at an appropriate level. Overall inventory management requires both knowledge of pharmaceutical usage and pharmaceutical returns. On-site inventories of expired pharmaceuticals will help to verify that the pharmaceutical returns companies are accounting for all returned drugs. The MTFs also need to track the cost and benefits of the program by monitoring and reconciling credits received. In addition, they need to analyze their returns data for trends that would indicate the need to change stock levels and pharmaceutical ordering requirements.

DoD needs to develop policy and establish oversight procedures to manage its pharmaceutical returns program.

Pharmaceutical Returns Policy

Written policy concerning the processing of expired pharmaceuticals is limited.¹³ The Office of the Assistant Secretary of Defense (Health Affairs) had not issued any policy regarding pharmaceutical returns. At the Military Department headquarters-level, Army Medical Command Operations Management Bulletin No. 10-02 provides guidance for handling pharmaceutical returns. The Bulletin tasks the pharmacy chief and the logistics chief at Army MTFs to ensure procedures are in place to track and obtain maximum credit for returned pharmaceuticals. Air Force Manual 23-110 provides information concerning the removal and return of expired items using commercial credit returns programs. The Naval Medical Command had not issued any policy regarding pharmaceutical returns. None of the Military Department policies address analyzing data on expired pharmaceuticals for trends applicable to inventory management.

Five of the nine MTFs visited had local policies that address the processing of pharmaceutical returns—two Army, two Navy, and one Air Force. The two Army policies include detailed procedures on the collection of expired pharmaceuticals and the pharmacy staff's interaction with the pharmaceutical returns company. One Navy policy and the Air Force policy merely mention that expired pharmaceuticals are to be returned. The other Navy policy includes general procedures for interacting with the pharmaceutical returns company. None of the policies discuss analyzing the information provided by pharmaceutical returns companies for trends applicable to inventory management.

¹³Although not policy, DSCP provides the PRMP contract and general information about the pharmaceutical returns program on its Internet site (<http://dmmonline.dscp.dla.mil/pharm/returnprog.asp>).

Oversight of the Pharmaceutical Returns Program

DoD does not provide sufficient oversight of the pharmaceutical returns program.

DSCP Oversight. Contract administration for the PRMP contract is the responsibility of DSCP. However, DSCP has provided little oversight of contract usage or contractor performance. DSCP representatives did not know how many MTFs used the PRMP contractor, the volume of returns, or the amount of credits. Although DSCP periodically receives summary reports from the contractor, it does not actively analyze or monitor those reports. DSCP officials stated that it is not DSCP's responsibility to track data. They stated that it is the MTF's responsibility to follow up on credits due. Also, the contract specifies that contractor invoicing and payment by prime vendors are business matters between the contractor and prime vendors and do not involve DSCP.

Although the Military Departments should take a more active role in the management of pharmaceutical returns, overall responsibility for contract oversight resides with DSCP. MTF staffs need to report any problems with the contractor through the formal reporting process and the Military Departments need to ensure DSCP is aware of any problems as soon as they are identified. However, we believe DSCP should oversee the PRMP contractor's performance, to include ensuring that the contractor provides its required services to the MTFs and that the MTFs are satisfied with services received.

Military Department Oversight. The Military Department pharmacy consultants were cognizant of the pharmaceutical returns process, but provided little guidance or oversight for managing the process at the MTF level. As noted in this report, at Military Department-headquarters level, the guidance is very general: two Military Departments stated expired drugs would be returned for credit. While the guidance at the MTFs visited was more specific, none addressed oversight of the pharmaceutical returns program. A recent General Accounting Office (GAO) report¹⁴ identified that the MTFs did not adequately manage their pharmaceutical returns. As a result of that report, the Navy included the expired pharmaceutical returns program as an optional assessable unit in its FY 2003 management control plan, and the Air Force included the program in its FY 2003 management control plan. Only one Navy MTF visited had conducted a self-evaluation of its expired pharmaceutical returns program; that MTF identified weaknesses in its processing of expired pharmaceuticals.

The GAO recommended that the MTFs prepare an inventory of expired pharmaceuticals before shipping them to a pharmaceutical returns company. We prepared such inventories at four of the MTFs visited. The inventory preparation was a lengthy process and it was extremely difficult to match our inventory to the one prepared by the pharmaceutical returns company. The inventory prepared by the pharmaceutical returns company identifies pharmaceutical manufacturers using corporate information that, in some cases, is different than the manufacturer identified on the pharmaceutical item. In addition, the pharmaceutical returns

¹⁴GAO Report No. GAO-03-168, "Military Treatment Facilities: Internal Control Activities Need Improvement," October 25, 2002.

company uses scanners, which decreases the amount of time required to prepare the inventory. We believe that instead of requiring each MTF to prepare its own inventory, the pharmaceutical returns company should be required to prepare an inventory at the time the expired pharmaceuticals are collected and that an MTF representative should be present when the inventory is taken to ensure all expired pharmaceuticals are identified. If the pharmaceutical returns company is unable to provide an inventory report to the MTF before returns are shipped, or the MTF elects to package its own returns, then the MTF staff would be required to prepare an inventory before shipping the expired pharmaceuticals. We contacted the GAO representative listed as the primary point of contact for the report. The representative agreed that our recommended approach was an acceptable alternative to having all MTFs prepare their own inventories.

Pharmaceutical Returns Program Cost Information. Key cost data concerning the pharmaceutical returns program was not easily retrievable and, in some cases, did not exist in any DoD or Military Department files or reports. We were unable to identify the funds expended for pharmaceutical returns services, and DoD did not centrally maintain information concerning the cost of the pharmaceutical returns program. Prime vendors are the primary payers for pharmaceutical returns services, generally making invoice payments from MTF credit accounts maintained by the prime vendors. A prime vendor we contacted to obtain information on payments made to pharmaceutical returns companies from the MTF credit accounts was unable to provide the data because its records do not track payments by client. The MTFs, the pharmacy consultants, the TMA pharmacy director, and DSCP staff also did not maintain the data.

DoD did not have complete and readily available information concerning pharmaceutical returns credits and payments. Information concerning actual credits is not centrally maintained. We requested MTF-level credit information from each Military Department pharmacy consultant, who in turn had to request the information from each MTF.

DoD Working Group

In 2002, DoD established a working group to study the future of the pharmaceutical returns program. The working group, called the DoD Pharmaceutical Reverse Distribution Working Group, was tasked with developing DoD policy and procedures regarding the pharmaceutical returns program. In addition, the working group was to identify requirements to be included in future contracts. The working group includes representatives from the Military Departments and DSCP. It is a joint effort between the pharmaceutical and logistics communities. We commend DoD for establishing a joint working group to address the problems associated with pharmaceutical returns.

Future Contracts for Processing Pharmaceuticals Returns

DoD and DVA should continue their coordinated effort for future Government contracts with pharmaceutical returns companies. Although DSCP is responsible for the PRMP contract, it may not be involved in future pharmaceutical returns contracts; therefore, DoD should provide DVA with its requirements for any new contracts, whether a stand-alone contract (such as the current PRMP contract) or as part of the Federal supply schedule. The following elements should be considered for future DoD contracting efforts.

- Payment to the contractor should not be made until credits are received and should be based on the actual credits, not estimated or anticipated credits, thereby increasing the contractor's incentive to obtain maximum credit amounts.
- A contractor representative should provide on-site services, whenever possible, and the contractor representative should be required to provide an inventory of all pharmaceuticals collected at the facility before they are boxed for shipment.
- The contractor should provide reports that will allow the MTF to track the pharmaceuticals eligible for credit from collection to receipt of actual credits. At a minimum, the report should include:
 - a list of returnable pharmaceuticals by manufacturer with estimated credits clearly identified,
 - a list of non-returnable pharmaceuticals with the cost for disposal,
 - credit reports showing both actual credits received and estimated credits, and
 - cost reports identifying contractor fees for each pharmaceutical collection.
- The contract should be mandatory; however, to ensure competition, there could be multiple awards.

The MTF also has obligations that need to be included in the contract. First, the pharmacy staff should pull the expired pharmaceuticals from the pharmacy inventory before the contractor arrives. The contractor should not be involved in the identification and removal of expired pharmaceuticals. Second, the MTF staff should be required to observe the inventory performed by the contractor.

Conclusion

With improved policy and oversight, DoD would have better control over DoD funds expended for pharmaceutical returns services and the credits received for returned pharmaceuticals. In addition, analyzing usage data as well as information collected from pharmaceutical returns reports would help MTFs

establish appropriate stock levels for pharmaceuticals, which would reduce the number of expired pharmaceuticals that are returned.

The President's Management Agenda, FY 2002, included nine agency-specific goals to improve Federal management of programs. One of the goals was to improve coordination of DoD and DVA programs and systems. The PRMP contract is a joint DoD/DVA initiative. We support that effort and believe any changes to the program should be coordinated between DoD and DVA. Therefore, we will provide a copy of this report to the DoD/DVA Joint Executive Council.

Recommendations, Management Comments, and Audit Response

B.1. We recommend that the Military Department Surgeons General direct military treatment facilities to either use the Pharmaceutical Returns Management Program contractor or have valid authorization for procuring and paying for the services received from another pharmaceutical returns company.

Military Department Comments. The Army concurred and stated that Army Medical Logistics has alerted pharmacies of the issue and will assist pharmacies in preparing statements of work and engaging with contracting offices to transition from service agreements to contracts. The Navy concurred but did not provide additional comments on the recommendation. The Air Force concurred, stating that Air Force Medical Logistics will assist in the transition from service agreements to contracts and will engage pharmaceutical returns vendors in a consultative role to overcome any potential problems.

Audit Response. The Army and the Air Force comments were fully responsive, and the Navy comments were partially responsive. We request that the Navy provide comments on how it plans to implement the recommendation in response to the final report.

B.2. We recommend that the Commander, Defense Supply Center Philadelphia:

a. Modify the pharmaceutical prime vendor contracts to:

(1) Allow for payments to pharmaceutical returns companies other than the Pharmaceutical Returns Management Program contractor.

(2) Allow the prime vendors to make payments to pharmaceutical returns companies only after verifying that a contract exists between the military treatment facility and the pharmaceutical returns company. If there is no contract, direct the prime vendors not to make payments from the military treatment facilities' credit accounts.

b. Provide oversight of the current Pharmaceutical Returns Management Program contract to ensure that the contractor provides the services and reports required by the contract.

Defense Logistics Agency Comments. The Defense Logistics Agency concurred. The Defense Logistics Agency stated that DSCP has already modified all current pharmaceutical prime vendor contracts to allow the use of the MTFs' prime vendor credit accounts to reimburse all authorized drug returns companies. In addition, DSCP has initiated procedures to verify that MTFs using non-PRMP companies have contracts with those companies before authorizing reimbursement through the credit accounts. Further, DSCP will oversee the performance of the PRMP contractor. The Defense Logistics Agency noted that DSCP is not responsible for overseeing the performance of non-PRMP companies.

Military Department Comments. Although not required to respond, the Army, the Navy, and the Air Force also concurred. The Army and Air Force stated that they had assigned pharmacists to the DoD working group that is developing requirements for new pharmaceutical returns contracts.

B.3. We recommend that the Military Department Surgeons General develop policy and establish oversight procedures to ensure that military treatment facility pharmacy or medical logistics staff:

a. Ensure an inventory of all returned pharmaceuticals is prepared or generated before the shipment leaves the facility.

b. Track the costs associated with their pharmaceutical returns services and the amount of credits to ensure the costs for the services provided are reasonable and the credits received are complete.

c. Analyze returned pharmaceuticals data for trends that indicate a need to modify inventory levels or ordering practices.

Military Department Comments. The Army and the Air Force concurred and stated that the DoD Pharmaceutical Reverse Distribution Working Group had developed a draft plan, currently in coordination among the Services, that will satisfy the intent of this recommendation. The Navy also concurred.

Audit Response. The Army and Air Force comments were fully responsive; however, we request clarification on how they plan to ensure that the costs of services provided by the pharmaceutical returns companies are reasonable. Because all elements of the recommendation were not specifically addressed in the responses, we will monitor the working group's progress to ensure that all elements of the recommendation are addressed. Corrective actions planned by the working group should apply to all three Military Departments. However, we request that the Navy provide comments in response to the final report indicating its intention to support the working group and to comply with its recommendations.

B.4. We recommend that the Assistant Secretary of Defense (Health Affairs) request that the Department of Veterans Affairs include the following provisions in future contracts for pharmaceutical returns services:

a. Payment to the contractor will not be made until the credits are received and will be based on the actual credits received.

b. A contractor representative will provide on-site services, whenever possible, and the contractor representative will provide an inventory of all pharmaceuticals collected at the facility before they are boxed for shipment.

c. The contractor will produce reports that will allow the pharmacy or logistics staff to track expired pharmaceuticals eligible for credit from collection to receipt of actual credits. The reports will, at a minimum, include information identifying returnable pharmaceuticals with estimated credits, non-returnable pharmaceuticals with the cost for disposal, actual credits received, and contractor fees for each collection of pharmaceuticals.

Military Department Comments. Although not required to respond, the Army, the Navy, and the Air Force concurred.

Audit Response. The Assistant Secretary of Defense (Health Affairs) did not provide comments. We request that the Assistant Secretary provide comments in response to the final report.

B.5. We recommend that the Assistant Secretary of Defense (Health Affairs) and the Military Departments require the military treatment facilities to use a pharmaceutical returns company that receives a contract when the next procurement for services is awarded.

Military Department Comments. The Army stated that the new contracts will be built on DoD policy requiring MTFs to have contracts with whatever pharmaceutical returns company it uses. The Navy concurred, but did not provide additional comments on the recommendation. The Air Force stated that the new contracts will be built on DoD policy and that there should be no reason to use any other contracts.

Audit Response. We consider the Army, the Navy, and the Air Force comments to be partially responsive. The intent of this recommendation is to make the use of any new national pharmaceutical returns contract, or contracts, mandatory. Implementation of the recommendation is dependent upon the responses of the Assistant Secretary of Defense (Health Affairs) to Recommendations B.4. and B.5. We request clarifying comments from the Military Departments, indicating whether they concur with mandating the use of national pharmaceutical returns contracts. The Assistant Secretary of Defense (Health Affairs) did not provide comments. We request that the Assistant Secretary provide comments in response to the final report.

Appendix A. Scope and Methodology

To understand DoD pharmacy inventory management procedures, including the expired pharmaceutical returns program and information systems supporting pharmacy management, we met with TMA personnel; Military Department pharmacy consultants; pharmacy managers and staff at 10 Military Department MTFs; and representatives at 2 pharmaceutical returns companies, 1 pharmaceutical prime vendor, and DSCP. In addition, to gain an understanding of pharmacy management procedures in the private sector, we contacted the pharmacy directors of three private-sector organizations that operate pharmacies. To learn about the DVA pharmacy program, we contacted the PRMP coordinator for the DVA and met with pharmacy staff at one DVA facility. The sites visited were:

- Military Treatment Facilities
 - 11th Medical Group Clinic, Bolling Air Force Base, Maryland
 - 347 Medical Group Clinic, Moody Air Force Base, Georgia
 - Andrew Rader Clinic, Fort Myer, Virginia
 - Lawrence Joel Army Health Clinic, Fort McPherson, Georgia
 - Madigan Army Medical Center, Fort Lewis, Washington
 - Michael O’Callahan Federal Hospital, Nellis Air Force Base, Nevada
 - National Naval Medical Center Bethesda, Maryland
 - Naval Air Station Clinic, North Island, Coronado, California
 - Naval Branch Medical Clinic, Dobbins Air Force Base, Marietta, Georgia
 - William Beaumont Army Medical Center, Fort Bliss, Texas
- Pharmaceutical Returns Companies
 - EXP Pharmaceutical Services Corporation, Fremont, California
 - Guaranteed Returns, Setauket, New York
- Pharmaceutical Prime Vendor – Cardinal Health, Dublin, Ohio
- Defense Supply Center Philadelphia, Pennsylvania

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- Private-Sector Organizations
 - Giant Headquarters, Landover, Maryland
 - Kaiser Permanente, Mid-Atlantic Regional Office, Rockville, Maryland
 - Walgreens, Pharmacy Marketing System, Deerfield, Illinois
 - Department of Veteran Affairs – Veterans Administration Medical Center, Washington, D.C.

At TMA, we met with the TMA pharmacy program director to gain knowledge of pharmacy management within DoD and with TMA systems managers and staff to identify the functional capabilities and implementation of CHCS and the DMLSS system as they relate to pharmacy inventory management. We met with the Military Department pharmacy consultants to better understand the Military Departments' pharmacy programs and the pharmacy consultants' role in the overall operation of MTF pharmacies. We judgmentally selected nine MTFs, selecting one hospital and two clinics from each Military Department. At the nine MTFs, we discussed five key issues—system support, inventory management, stock levels, expiration dates, and the expired pharmaceutical returns program. We visited a 10th MTF (Madigan Army Medical Center) to interview pharmacy staff and determine whether the unique inventory management system used at the facility was relevant to the overall audit objective. In addition, at the original nine MTFs, we observed the ordering, receiving, and stocking of pharmaceuticals. We also inventoried expired pharmaceuticals at four MTFs, two for each pharmaceutical returns company visited, to determine the value and viability of the requirement for MTFs to prepare pre-shipment inventories. Further, at five MTFs, we checked the stock levels of certain pharmaceuticals that we judgmentally selected and compared their on-hand levels with usage reports from CHCS to determine whether pharmaceutical stock levels were maintained at the levels stated by the MTFs.

We met with representatives from two pharmaceutical returns companies that service DoD clients, including the PRMP contractor, to determine how they interact with MTF staff, how they support the MTF regarding the identification and management of credits received for returned expired pharmaceuticals, and how they were reimbursed for their services. We met with representatives from one prime vendor to determine how the vendor is involved with the DoD pharmaceutical returns process. We met with representatives at DSCP to obtain information concerning the award and administration of the PRMP contract. We contacted the private-sector organizations to better understand how they handle inventory management and their pharmaceutical returns program. We met with DVA pharmacy staff to understand their processes concerning inventory management and to determine their satisfaction level with the PRMP contractor.

To better understand the requirements for pharmacy inventory management and the handling of returned expired pharmaceuticals, we reviewed DoD, Military Department, and MTF policies, procedures, and reports. The documents and reports we reviewed were dated from January 1995 through January 2004.

We used Government purchase card data to identify potential split payments. Specifically, we selected transactions processed over a designated time period to specific vendors, examined the data for instances of multiple transactions on the same day to the same vendor, and determined whether the total of those transactions exceeded the purchase card limit. We did not follow up with MTF personnel to document the potential improper payments.

To better understand the cost of pharmaceuticals and credits received at the MTFs, we requested FY 2002 pharmaceutical expenditure and returns credit information from the Military Departments. We did not validate the data provided by the Military Departments.

We performed this audit from April 2003 through March 2004 in accordance with generally accepted government auditing standards. We did not review the inventory management of controlled pharmaceuticals because prior Military Department audits addressed the issue. Further, storage and management of controlled drugs is overseen by the Drug Enforcement Administration and the Joint Commission on Accreditation of Healthcare Organizations. In addition, because of the small number of facilities visited and the small number of pharmaceuticals selected, information in the report concerning days' stock on-hand cannot be assumed to reflect days' stock on-hand at all DoD pharmacies.

Use of Computer-Processed Data. To achieve the audit objective, we relied on computer-processed data from CHCS. We used the data to assess and compare inventory levels of selected pharmaceuticals. We did not perform a formal reliability assessment of the computer-processed data; however, any errors in the CHCS data would not change the conclusions in this report. We also relied on computer-processed Government purchase card data from Citibank and U.S. Bank, which were provided to us by the Defense Manpower Data Center. We did not perform a formal reliability assessment of the purchase card data because validation of the data was outside the scope of the audit.

General Accounting Office High-Risk Area. The General Accounting Office has identified several high-risk areas in DoD. This report provides coverage of the Defense Inventory Management high-risk area.

Management Control Program Review

DoD Directive 5010.38, "Management Control (MC) Program," August 26, 1996, and DoD Instruction 5010.40, "Management Control (MC) Program Procedures," August 28, 1996, require DoD organizations to implement a comprehensive system of management controls that provides reasonable assurance that programs are operating as intended and to evaluate the adequacy of the controls.

Scope of the Review of the Management Control Program. We reviewed the adequacy of TMA, Military Department, and MTF management control plans for pharmacy inventory management and the self-evaluation at one MTF that addressed pharmaceutical returns.

Adequacy of Management Controls. We identified a material management control weakness at TMA and the Military Departments, as defined by DoD Instruction 5010.40. TMA and the Military Departments did not establish management controls for pharmacy inventory management to ensure the stock levels of pharmaceuticals on-hand were not excessive, which would minimize the number of expired pharmaceuticals left on the shelf. Recommendation A.1., if implemented, will correct the identified weakness and could result in more effective management of pharmaceutical inventories. A copy of the report will be provided to the senior officials responsible for management controls in TMA and the Military Departments.

Adequacy of Management's Self-Evaluation. In FY 2003, the Navy and the Air Force identified expired pharmaceutical returns as an assessable unit for the MTFs. However, only one MTF visited had completed a self-evaluation. That MTF identified weaknesses in its processing of pharmaceutical returns. Because of the limited scope of their reviews, the Military Departments did not identify or report the material management control weakness identified by the audit. TMA and Military Department officials did not identify inventory management as an assessable unit and, therefore, did not identify or report the material management control weakness identified by the audit.

Appendix B. Prior Coverage

During the last 5 years, the GAO, the Inspector General of the Department of Defense (IG DoD), the Army Audit Agency, and the Air Force Audit Agency have issued 17 reports discussing pharmacy inventory management. Unrestricted GAO reports can be accessed over the Internet at <http://www.gao.gov>. Unrestricted IG DoD reports can be accessed at <http://www.dodig.osd.mil/audit/reports>.

GAO

GAO Report No. GAO-03-168, "Military Treatment Facilities: Internal Control Activities Need Improvement," October 25, 2002

IG DoD

IG DoD Report No. D-2002-094, "Pricing of Pharmaceutical Items in the Medical Prime Vendor Program," May 23, 2002

Army Audit Agency

Army Audit Agency Report No. AA-02-129, "Pharmaceutical Management, U.S. Army Medical Command," January 25, 2002

Air Force Audit Agency

Air Force Audit Agency Report No. F2003-0021-FDW000, "Pharmacy Operations: 6th Air Mobility Wing, MacDill AFB [Air Force Base], FL," March 12, 2003

Air Force Audit Agency Report No. F2003-0019-FBN000, "Pharmacy Operations: 3rd Wing Elmendorf AFB, AK," December 23, 2002

Air Force Audit Agency Report No. F2003-0009-FDN000, "Pharmacy Operations: 89th Airlift Wing, Andrews AFB, MD," December 3, 2002

Air Force Audit Agency Report No. F2003-0010-FDW000, "Pharmacy Operations: 45th Space Wing, Patrick AFB, FL," December 2, 2002

Air Force Audit Agency Report No. F2003-0012-FDM000, "Pharmacy Operations and Controlled Substances: 1st Fighter Wing, Langley AFB, VA," November 26, 2002

Air Force Audit Agency Report No. F2002-0052-WS0000, "Pharmacy Operations: 375th Airlift Wing, Scott AFB, IL," September 16, 2002

Air Force Audit Agency Report No. F2002-0032-WP0000, "Pharmacy Operations: 810th Medical Operations Squadron, Peterson AFB, CO," April 4, 2002

Air Force Audit Agency Report No. F2002-0023-WS0000, "Pharmacy Operations: 82d Training Wing, Sheppard AFB, TX," February 28, 2002

Air Force Audit Agency Report No. F2002-0020-EA0000, "Management of Pharmacy Operations: 11th Wing, Bolling AFB, DC," January 23, 2002

Air Force Audit Agency Report No. WR001024, "Pharmacy Operations: 59th Medical Wing, Lackland AFB, TX," June 21, 2001

Air Force Audit Agency Report No. ER001025, "Pharmacy Operations: 470th Air Base Squadron, Geilenkirchen - NATO Air Base, Germany" May 17, 2001

Air Force Audit Agency Report No. DW001009, "Pharmacy Operations: 74th Medical Group, Wright-Patterson AFB, OH," December 27, 2000

Air Force Audit Agency Report No. WS001005, "Pharmacy Operations: 97th Air Mobility Wing, Altus AFB, OK," October 19, 2000

Air Force Audit Agency Report No. DH000017, "Pharmacy Inventory Controls: 66th Air Base Wing, Hanscom AFB, MA," June 21, 2000

Appendix C. Pharmacy Boards and Committees

There are four boards or committees that provide guidance regarding MTF pharmacy policy and procedures.

DoD/DVA Federal Pharmacy Executive Steering Committee. The Committee recommends improvements to the pharmacy benefits for DoD and DVA beneficiaries and oversees joint actions of the two Departments to eliminate redundancies in contracting and utilization management. Members include two co-chairs—Chairperson, DoD Pharmacy Board of Directors (DoD) and Chief Consultant for Pharmacy Benefits Management (DVA). Each Department also has three to five additional Committee members.

DoD Pharmacy and Therapeutics Committee. The Committee develops and reviews the uniform formulary of pharmaceuticals for DoD. The Committee consists of voting and non-voting members, as specified in its charter, drawn from the Military Departments, DVA, and TRICARE network providers.

DoD Pharmacoeconomic Center. The Center focuses on improving the clinical, economic, and humanistic outcomes of drug therapy in support of the readiness and managed care mission of the Military Health System. Additionally, the Center supports joint DoD/DVA initiatives. Its membership includes at least one military physician, one pharmacist, and one enlisted pharmacy technician from each Military Department.

DoD Pharmacy Board of Directors. The Board is the functional proponent for pharmacy operations policy and business process improvements in support of the Executive Director, TMA. The Board provides direction to the DoD Pharmacoeconomic Center concerning functional requirements and standardized business practices. Membership includes the pharmacy consultants to the Surgeons General, as voting members, and the Director, DoD Pharmacy Programs, as a non-voting member.

Appendix D. Shelf Stock Reviews at Clinics Visited

Results of Comprehensive Shelf Stock Reviews at Clinics Visited*			
<u>Clinic</u>	<u>Approximate Number of Stocked Pharmaceuticals</u>	<u>Instances of First-in, First-out Noncompliance</u>	<u>Instances of Expired Pharmaceuticals</u>
Clinic 1	1,400	42	13
Clinic 2	200	21	54
Clinic 3	1,000	50	11
Clinic 4	600	42	2
Clinic 5	700	15	9
Clinic 6	Not Known	19	9
* A comprehensive shelf stock review was not performed at the hospitals; therefore, only the results for the clinics are provided.			

Appendix E. Pharmaceutical Expenditures and Credits Received Information

The following table is based on information requested from and provided by the Military Department pharmacy consultants. The Army was unable to provide information on credits received.

Fiscal Year 2002 Pharmaceutical Expenditures and Credits Received			
<u>Military Department</u>	<u>in millions</u>		<u>Credits as Percent of Expenditures</u>
	<u>Expenditures</u>	<u>Credits Received</u>	
Army	\$513.5	Not Available	Not Available
Navy	396.3	\$3.6	.92
Air Force	492.4	5.4	1.10
Total	\$1,402.2¹	\$9.1¹	1.02²

¹Difference between line items and total due to rounding.
²Total percent based on only Navy and Air Force expenditures and credits data.

Appendix F. Pharmaceutical Returns Management Program Contract

Contractor Responsibilities

The specific responsibilities of the PRMP contractor include regulatory compliance and registration, shipping and processing arrangements, establishment of estimated return value, disposal of non-returnable pharmaceuticals, and reporting and reconciliation.

Regulatory Compliance and Registration. The contractor is responsible for complying with all Federal and State regulations that pertain to drugs, hazardous materials, environmental protection, and transportation. In addition, all necessary permits and licenses required by Federal, State, and local authorities must be acquired and maintained by the contractor for the life of the contract. The contractor must be a licensed Drug Enforcement Administration registrant for handling controlled substances.

Shipping and Processing Arrangements. The returning facility (for example, the MTF) contacts the contractor directly to arrange for a return shipping date. The contractor furnishes all instructions, forms, labels, containers, and shipping supplies needed. If requested, and at additional cost, the contractor provides support on-site to inventory and prepare products for shipment to the contractor's facility for processing. All shipping costs within the continental United States are the responsibility of the contractor. The contractor is required to process all pharmaceuticals for credit or destruction within 30 days after receipt of the returned goods.

Establishment of Estimated Return Value. The contractor is required to compute the ERV for pharmaceuticals in accordance with contract guidance. The ERV is to be based on the DVA current purchase price, which is updated daily.

Disposal of Non-Returnable Pharmaceuticals. The contractor is required to list items that cannot be returned to the manufacturer on a separate disposal manifest. The contractor provides additional manifests for controlled drugs and when destroying hazardous waste products. The contractor provides a certificate of destruction to the returning facility within 30 days of destruction.

Reporting and Reconciliation. The contractor is required to provide to the returning facility detailed reports on returned goods, by manufacturer, within 30 calendar days after receiving the returned pharmaceuticals. The reports include the invoice number, product name, national drug code, lot or batch number, quantity, and ERV. In addition, the contractor must provide to the returning facility a monthly status report of credit receipts, listing the manufacturer, ERV, actual return value, and pending credits. Monthly reconciliation reports are to be provided for all accounts individually and a summary report is provided to the DSCP contracting officer. Reports are to show, at a minimum, the ERV for pharmaceuticals destroyed, fees for services rendered,

credits received, and credits pending. The contractor is also responsible for contacting the manufacturer to assist in resolving issues of inadequate or non-payment of outstanding credits.

Contractor Payments

The basic PRMP contract stated that the contractor would be paid a percentage of the ERV for each type of returnable pharmaceutical. However, an addendum to the contract states that the contractor should invoice and arrange for payment for all services through the applicable prime vendor. Based on that addendum, GRx receives its service fees from the prime vendor after credits are actually received. GRx bills on a monthly basis based on a percentage of the actual credits, plus the disposal fees for the non-returnable pharmaceuticals. The prime vendor stated that a percentage of the credits received from the manufacturer is deducted to pay the contractor's fees.

The processing fees for the current option period are 7.4 percent of credits for controlled substances and 7.1 percent for non-controlled substances. Fees for the optional on-site service are based on the location of the returning facility. The on-site service fees are 1.5 percent of credits for the continental United States; 2.5 percent of credits for Alaska, Hawaii, Puerto Rico, Guam, and the Philippines; and 3.5 percent of credits for other locations. The disposal fees for all non-returnable pharmaceuticals are \$2.62 per pound for hazardous waste and \$0.32 per pound for non-hazardous waste. The contractor does not charge the returning facility an additional processing fee for non-returnable pharmaceuticals.

Appendix G. Memorandum to the Military Department Surgeons General



INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-4704

DEC 17 2003

MEMORANDUM FOR SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE

SUBJECT: Improper Payments Being Made on Behalf of Military Treatment Facilities
to Pharmaceutical Reverse Distributors

During our audit of pharmaceutical inventory management at military treatment facilities (MTFs), Project No. D2003LF-0109, we discovered that at least one pharmaceutical prime vendor was making improper payments to at least two pharmaceutical reverse distributors (hereinafter referred to as drug return companies) for services provided to DoD customers.¹ The prime vendor contracts allow payments from credit accounts² only to Guaranteed Returns, the recipient of the national Pharmaceutical Returns Management Program (PRMP) contract. However, prime vendors are making payments from the credit accounts to other drug return companies. According to the prime vendors contacted, they have received either written or verbal approval from the DoD customers to make payments to drug return companies on their behalf. However, we could not find authority in the prime vendor contract to allow for such payments. Therefore, we have requested that the Defense Supply Center Philadelphia direct the prime vendors to immediately stop payments to non-PRMP drug return companies.

Further, we identified two additional problems at the MTFs regarding the receipt of services from non-PRMP drug return companies. First, at the two MTFs we visited that used a non-PRMP drug return company (one Navy, one Air Force), neither had a local contract for the services received or to allow for the payment of those services. Second, our review of government purchase card usage identified 14 MTFs that, in FY 2003, appeared to have violated acquisition policy by paying for drug return company services using split payments (that is, multiple payments on the same day, each under the micro-purchase threshold). Although we did not visit an Army site that used a non-PRMP drug return company, we were informed by one drug return company that it had Army clients and the billing method used, either using the government purchase card or invoices to prime vendors, was the same as for the company's other DoD clients.

As a result of our findings, we are requesting that you direct each DoD customer within your Military Department that is not using the PRMP contract to have valid

¹DoD customers include MTF pharmacies and military units that maintain pharmaceutical war readiness material.

²Credit accounts are maintained by the prime vendors for each DoD customer that receives credits from drug manufacturers for returned drugs.

authorization for procuring and paying for the services of the non-PRMP drug return company and that payments to non-PRMP drug return companies will no longer be allowed from the prime vendors' DoD customers credit accounts.

Because the improper payment problem requires timely action, we are notifying you of the problem through this memorandum. We will include the issue in our overall report. We will also include in the report any actions taken to resolve the problem. Therefore, please provide a response by January 9, 2004, identifying the actions taken by your office regarding this issue.

If you have any questions or concerns regarding this request, please contact Ms. Betsy Brilliant at (703) 604-8875 or Ms. Carol Gorman at (703) 604-8775. Thank you for your support in this matter.

By direction of the Deputy Inspector General for Auditing:



Shelton R. Young
Director, Readiness and
Logistics Support Directorate

cc: Director, TRICARE Management Activity

Appendix H. Memorandum to the Commander, Defense Supply Center Philadelphia



INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
400 ARMY NAVY DRIVE
ARLINGTON, VIRGINIA 22202-4704

DEC 17 2003

MEMORANDUM FOR COMMANDER, DEFENSE SUPPLY CENTER
PHILADELPHIA

SUBJECT: Improper Payments Being Made by the Pharmaceutical Prime Vendors to
Pharmaceutical Reverse Distributors

During our audit of pharmaceutical inventory management at military treatment facilities (MTFs), Project No. D2003LF-0109, we discovered that at least one pharmaceutical prime vendor was making improper payments to at least two pharmaceutical reverse distributors (hereinafter referred to as drug return companies) for services provided to DoD customers.¹ The prime vendor contracts allow payments from credit accounts² only to Guaranteed Returns, the recipient of the national Pharmaceutical Returns Management Program (PRMP) contract. However, prime vendors are making payments from the credit accounts to other drug return companies. According to the prime vendors contacted, they have received either written or verbal approval from the DoD customers to make payments to drug return companies on their behalf. However, we could not find authority in the prime vendor contract to allow for such payments. Further, for the two MTFs we visited that used a non-PRMP drug return company, neither had a local contract to allow payment for those companies' return drug services.

We are requesting that you direct the prime vendors to immediately stop payments to the non-PRMP drug return companies. In addition, we request that you direct the prime vendors to notify the non-PRMP drug return companies that the prime vendors will no longer be allowed to make payments for invoices associated with DoD customers. We are also notifying the Surgeons General that payments for return drug services, except for services provided by Guaranteed Returns, were improper and payments will no longer be allowed from the prime vendors' DoD customer credit accounts, unless a contract is in place to support the payments.

Because the improper payment problem requires timely action, we are notifying you of the problem through this memorandum. We will include the issue in our overall report. We will also include in the report any actions taken to resolve the problem. Therefore, please provide a response by January 9, 2004, identifying the actions taken by your office regarding this issue.

¹DoD customers include MTF pharmacies and military units that maintain pharmaceutical war readiness material.

²Credit accounts are maintained by the prime vendors for each DoD customer that receives credits from drug manufacturers for returned drugs.

If you have any questions or concerns regarding this request, please contact Ms. Betsy Brilliant at (703) 604-8875 or Ms. Carol Gorman at (703) 604-8775. Thank you for your support in this matter.

By direction of the Deputy Inspector General for Auditing:



Shelton R. Young
Director, Readiness and
Logistics Support Directorate

cc: Director, Defense Logistics Agency
Director, TRICARE Management Activity
Director, Defense Supply Center
Philadelphia Internal Review

Appendix I. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)/Chief Financial Officer
Deputy Chief Financial Officer
Deputy Comptroller (Program/Budget)
Under Secretary of Defense for Personnel and Readiness
Assistant Secretary of Defense (Health Affairs)

Department of the Army

Assistant Secretary of the Army (Financial Management and Comptroller)
Surgeon General of the Army
Auditor General, Department of the Army

Department of the Navy

Assistant Secretary of the Navy (Manpower and Reserve Affairs)
Naval Inspector General
Surgeon General of the Navy
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Surgeon General of the Air Force
Auditor General, Department of the Air Force

Combatant Command

Inspector General, U.S. Joint Forces Command

Other Defense Organizations

Director, Defense Logistics Agency
Commander, Defense Supply Center Philadelphia

Non-Defense Federal Organizations

Office of Management and Budget
Deputy Secretary of Veterans Affairs
Department of Defense/Department of Veterans Affairs Joint Executive Council

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Government Reform
House Subcommittee on Government Efficiency and Financial Management, Committee on Government Reform
House Subcommittee on National Security, Emerging Threats, and International Relations, Committee on Government Reform
House Subcommittee on Technology, Information Policy, Intergovernmental Relations, and the Census, Committee on Government Reform

Defense Logistics Agency Comments



DEFENSE LOGISTICS AGENCY
HEADQUARTERS
8725 JOHN J. KINGMAN ROAD, SUITE 2533
FORT BELVOIR, VIRGINIA 22060-6221

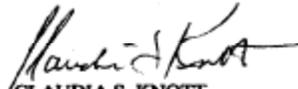
APR 30 2004

IN REPLY
REFER TO J-3

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL FOR AUDITING
DEPARTMENT OF DEFENSE

SUBJECT: DoD Management of Pharmaceutical Inventory and Processing of Returned
Pharmaceuticals (Project No. D2003LF-0109)

This is in response to subject draft report dated March 1, 2004. If you have any
questions, please contact Mrs. Sheila Raines, (703) 767-6282.


CLAUDIA S. KNOTT
Deputy Director
Logistics Operations

Attachment

DoD IG Draft Report
DoD Management of Pharmaceutical Inventory and Processing of Returned
Pharmaceuticals
Project No. D2003LE-0109, March 1, 2004

DoD-IG Finding: Although DoD has a national contract for processing pharmaceutical returns and has established a working group to address contract issues, improvements are needed in the implementation and management of DoD's pharmaceutical returns program. Specific findings include:

- The Pharmaceutical Returns Management Program (PRMP) contractor did not perform all the services required by its contract, and pharmacy staffs at three MTFs visited were not aware of all the services available to them in the PRMP contract and had not requested essential services.
- Of the nine MTFs visited, two chose not to use the PRMP contractor. Those two MTFs did not have a legal contract with the pharmaceutical returns company (non-PRMP company) servicing them.
- A pharmaceutical prime vendor was paying at least two non-PRMP companies from MTF credit accounts when it did not have contractual authority to make such payments.
- Fourteen MTF pharmacies made payments in FY 2003 to a non-PRMP company through potentially improper use of the Government purchase card program.
- MTFs did not conduct inventories of expired pharmaceuticals being returned for credit, track the credits associated with the returned pharmaceuticals, or analyze returns data for trends applicable to inventory management.

DoD needs to develop policy and establish oversight procedures to manage its pharmaceutical returns program. With improved policy and oversight, DoD could have better control over DoD funds expended for pharmaceutical returns services and the credits received for returned pharmaceuticals. In addition, MTF management of pharmaceutical inventory would be improved, reducing the number of pharmaceuticals that will ultimately expire and have to be returned.

DLA Comments:

Concur. DSCP agrees that DoD needs to develop policy and establish oversight procedures to manage its pharmaceutical returns program. While DSCP agrees with the DoD-IG, it is important to note that Program Management of the drug return process is the responsibility of the Military Services. DSCP awarded the PRMP contract in order to provide a contract vehicle that MTFs may use to process their

drug returns. It is not a mandatory contract and MTFs may contract with other companies to provide drug return services; however, DSCP is not responsible for oversight of these non-PRMP contracts. DSCP responsibilities are to ensure that the PRMP contractor is performing in accordance with the terms and conditions of the contract; ensure that MTFs are aware of the terms and conditions of the contract, if they elect to use it (PRMP contract has been posted on the DSCP web site); advise MTFs of the various services and reports provided by the PRMP contractor; and ensure that the Pharmaceutical Prime Vendors (PPV) comply with the terms of the PPV contract when using a MTF's credit account to pay for services performed by a drug return contractor. Any disputes between MTFs and the PRMP contractor or other authorized contractor, arising from the processing of returnable pharmaceuticals and/or the disposal of non-returnable pharmaceuticals owned by the MTFs, are negotiated solely by these parties. DSCP does not intervene in, or settle such disputes. DSCP has modified all current Pharmaceutical Prime Vendor (PPV) contracts to incorporate the recommendations of the DoD-IG, (see recommendations and DLA Comments below). In addition, DSCP will notify the MTFs and the PPVs of their responsibilities in using MTF credit accounts to pay for services performed by a non-PRMP contractor (see below).

DoD-IG Recommendations to the Commander, Defense Supply Center Philadelphia:

1. Modify the pharmaceutical prime vendor contracts to:
 - a. Allow for payments to pharmaceutical returns companies other than the PRMP contractor.
 - b. Allow for payments to pharmaceutical returns companies other than the Pharmaceutical Returns Management Program contractor. Allow the prime vendors to make payments to pharmaceutical returns companies only after verifying that a contract exists between the military treatment facility and the pharmaceutical returns company. If there is no contract, direct the prime vendors not to make payments from the military treatment facilities' credit accounts.

DLA Comments:

Concur. The current PRMP contract is not a requirements contract and other reverse distributors are widely used throughout DoD. DSCP has modified all current Pharmaceutical Prime Vendor (PPV) contracts to allow the PRMP drug return company, as well as other drug return companies with local MTF contracts, reimbursement through the MTF's prime vendor credit account. Accordingly, prime vendors will not be allowed to pay for services performed by non-contracted drug return companies. In addition, DSCP will notify all MTFs that if they want to use their credit accounts to pay for services performed by a non-PRMP company, then

they must establish a contract with the non-PRMP company and forward it to DSCP for verification prior to utilizing the contract. DSCP will review the contract and, if acceptable, notify the PPV. Also, all PPVs will be instructed to contact DSCP for verification of a non-PRMP contract before issuing payment from the MTFs credit account to a non-PRMP contractor.

Disposition:

- Action is ongoing
- Action is considered complete

2. Provide oversight of the current Pharmaceutical Returns Management Program contract to ensure that the contractor provides the services and reports required by the contract.

DLA Comments:

Concur. DSCP will work with the PRMP contractor and the Military Health Service community to educate our customers about the services and reports available in the PRMP contract. DSCP will solicit feedback from the customers on current PRMP contractor performance and the adequacy of the services and reports currently being provided by the PRMP contractor. DSCP will continue to work with the PRMP contractor to ensure that they are meeting the needs of DoD customers within the scope of the PRMP contract. In addition, the DoD working group is conducting market research to identify all the drug return services and reports required by the customers for inclusion in future drug return contracts. DSCP will only provide oversight on services and reports provided by the PRMP contractor. DSCP is not responsible for oversight of non-PRMP contracts and services.

Disposition:

- Action is ongoing
- Action is considered complete

Department of the Army Comments



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

DASG-IRO

30 April 2004

MEMORANDUM THRU Assistant Secretary of the Army (Manpower and Personnel)
Pentagon, Washington, DC 20310

John P. McLaurin III
John P. McLaurin III
Deputy Assistant Secretary
(Human Resources)

FOR Mr. Michael A. Joseph, Program Director, Readiness and Logistics Support Directorate,
Inspector General, Department of Defense, 400 Army Navy Drive, Arlington, VA 22202-4704

SUBJECT: Report on DoD Management of Pharmaceutical Inventory and Processing of Returned
Pharmaceuticals (Project No. D2003LF-0109)

1. Thank you for the opportunity to review this draft report. We concur with the report and
recommendations as presented. Copies of our specific comments and a draft Pharmacy-Owned
Drug Reverse Distribution Process are attached for your consideration.

2. Questions regarding this action should be directed to COL Mike Heath, Pharmacy Consultant,
Health Policy and Services, Office of The Surgeon General, DSN 761-5959 or Commercial (703)
681-5959.

FOR THE SURGEON GENERAL:

Atch
as

Kenneth L. Farmer, Jr.
KENNETH L. FARMER, JR., M.D.
Major General
Deputy Surgeon General

INSPECTOR GENERAL, DEPARTMENT OF DEFENSE (IG, DoD) DRAFT REPORT
MARCH 1, 2004 (PROJECT NO. D2003LF-0109)

REPORT ON DOD MANAGEMENT OF PHARMACEUTICAL INVENTORY AND
PROCESSING OF RETURNED PHARMACEUTICALS

DEPARTMENT OF THE ARMY (USA MEDCOM) COMMENTS
TO THE IG, DOD RECOMMENDATIONS

RECOMMENDATION A.1: We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Department Surgeons General, develop policy and procedures that:

- a. Require the military treatment facilities to:
 - (1) Establish stock levels based on facility workload, scope, level of care, and mission.
 - (2) Require the facility to validate the stock levels on a periodic basis.
- b. Standardize the criteria for identifying the expiring pharmaceuticals and removing those pharmaceuticals from inventory.
- c. Establish standard procedures for stocking pharmaceuticals on the shelves to ensure those with the earliest expiration date are dispensed first.
- d. Establish oversight procedures to ensure the policy and procedures are implemented and follow.

ARMY RESPONSE: Concur. The Army Medical Department is developing a corporate process for improvements to all aspects of pharmaceutical inventory management including but not limited to expired / suspended / recalled pharmaceuticals. Additionally, the Army is revising the primary pharmacy management regulation, Chapter 11 to AR 40-3 (Pharmacy management), which will have a significantly detailed section on pharmaceutical inventory management. Final input to this revision is due 30 April 2004.

RECOMMENDATION A.2: We recommend that the Assistant Secretary of Defense (Health Affairs) ensure the upgraded pharmacy component of the Composite Health Care System II:

- a. Interfaces with the Defense Medical Logistics Standard Support system for automatic ordering.
- b. Incorporates a capability to automatically identifying expiring or expired pharmaceutical, when expiration date information is embedded in pharmaceutical product labels.

ARMY RESPONSE: Concur. The Army supports an automated solution for pharmacy inventory control. The new pharmacy module for CHCS should accomplish this function.

RECOMMENDATION B.1: We recommend that the Military Department Surgeons General direct military treatment facilities to either use the Pharmaceutical Returns Management Program contractor or have valid authorization for procuring and paying for services received from another pharmaceutical returns company.

ARMY RESPONSE: Concur. Army Medical Logistics alerted medical logistics and pharmacy accounts of this issue. Army Medical Logistics will assist medical logistics and pharmacy pharmaceutical reverse distribution accounts in preparing statements of work and engaging with contracting offices to obtain a smooth transition from service agreements to contracts.

RECOMMENDATION B.2: We recommend that the Commander, Defense Supply Center Philadelphia:

a. Modify the pharmaceutical prime vendor contracts to:

(1) Allow for payments to pharmaceutical returns companies other than the Pharmaceutical Returns Management Program contractor.

(2) Allow the prime vendors to make payments to pharmaceutical returns companies only after verifying that a contract exists between the military treatment facility and the pharmaceutical returns company. If there is no contract, direct the prime vendors not to make payments from the military treatment facilities' credit accounts.

b. Provide oversight of the current Pharmaceutical Returns Management Program contract to ensure that the contractor provides the services and reports by the contract.

ARMY RESPONSE: Concur. The Army has assigned a pharmacist to the DMLSS and the DoD Pharmaceutical Reverse Distribution Working Group in September 2002. These working groups have been working with Defense Supply Center Philadelphia (DSCP) to ensure implementation of the correct oversight for pharmaceutical contracts. All the services' pharmacy consultants met with DSCP on 6 November 2003 to discuss requirements for new pharmaceutical returns contracts. They will continue to work with DSCP to ensure future contracts include all necessary requirements.

RECOMMENDATION B.3: We recommend that the Military Department Surgeons General develop policy and establish oversight procedures to ensure that military treatment facility pharmacy or medical logistics staff:

a. Ensure an inventory of all returned pharmaceuticals is prepared or generated before the shipment leaves the facility.

b. Track the costs associated with their pharmaceutical returns services and the amount of credits to ensure the costs for the services provided are reasonable and the credits received are complete.

c. Analyze returned pharmaceuticals data for trends that indicate a need to modify inventory levels or ordering practices.

ARMY RESPONSE: Concur. The DOD Pharmaceutical Reverse Distribution Working Group, which originated as an Air Force initiative, has developed a draft plan, currently in coordination among the services that fully concurs and will satisfy the intent of this recommendation. A flow chart of the proposed (DRAFT) process is attached to this document. A government-supervised 100% inventory will be completed before the vendor leaves the facility. Quarterly credit statements will be reconciled with a baseline inventory for one year; and, after a year, if the estimated credits have not arrived, MTFs will contact vendor to resolve or explain. The working group is still determining the appropriate percentage of estimated credits to be used based on rational explanation of what industry can accommodate. While the working group has yet to discuss specifics of the content of vendor-provided reports, the intended use of a vendor-provided report would be to seek ways to improve inventory and process efficiency. Policy to be generated by this working group will include guidance on use of vendor-provided reports.

RECOMMENDATION B.4: We recommend that the Assistant Secretary of Defense (Health Affairs) request that the Department of Veterans Affairs include the following provisions in future contracts for pharmaceutical returns services:

a. Payment to the contractor will not be made until the credits are received and will be based on the actual credits received.

b. A contractor representative will provide on-site services, whenever possible, and the contractor representative will provide an inventory of all pharmaceuticals collected at the facility before they are boxed for shipment.

c. The contractor will produce reports that will allow the pharmacy or logistics staff to track expired pharmaceuticals eligible for credit from collection to receipt of actual credits. The reports will, at a minimum, include information identifying returnable pharmaceuticals with estimated credits, non-returnable pharmaceuticals with the cost of disposal, actual credits received, and contractor fees for each collection of pharmaceuticals.

ARMY RESPONSE: Concur

RECOMMENDATION B.5: We recommend that the Assistant Secretary of Defense (Health Affairs) and the Military Departments require the military treatment facilities to use a pharmaceutical returns company that receives a contract when the next procurement for services is awarded.

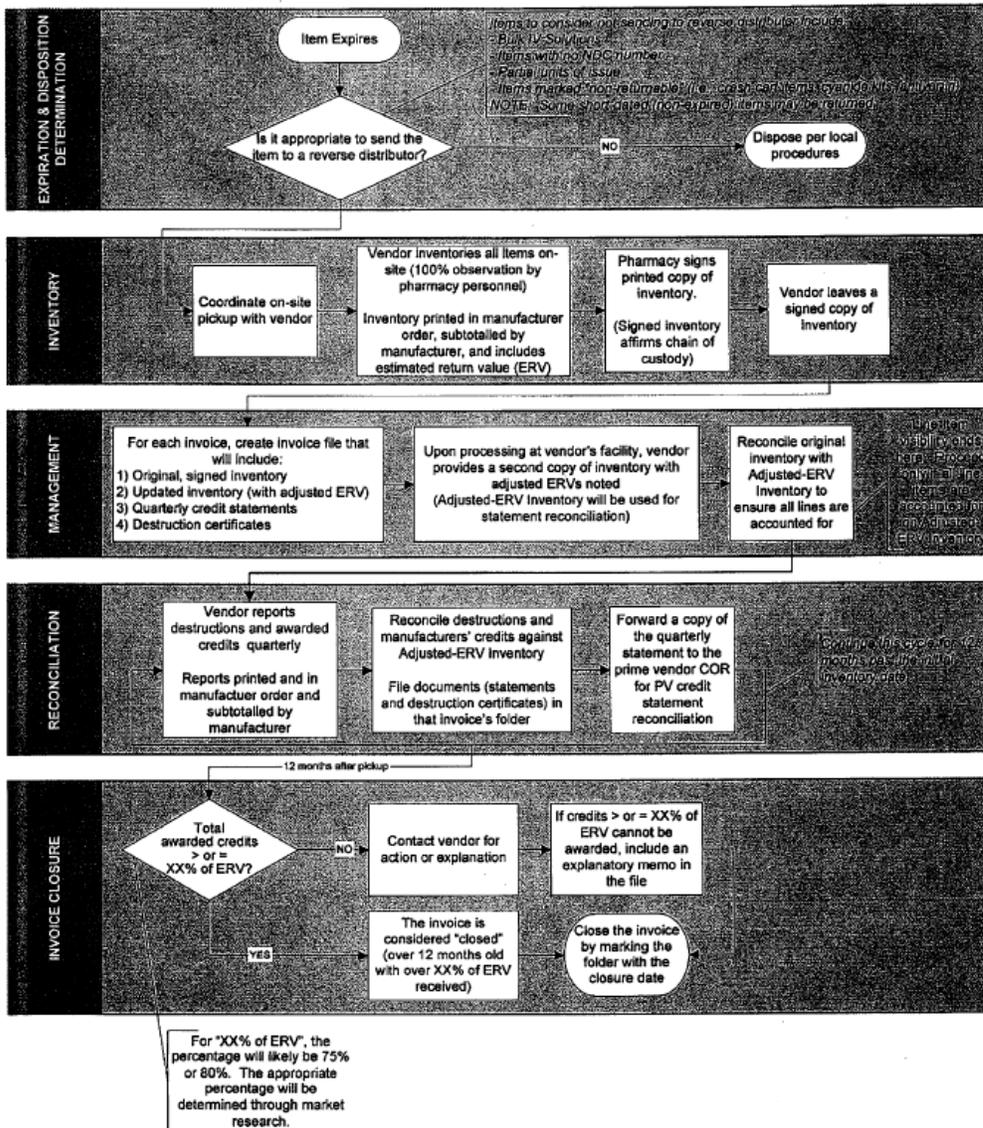
ARMY RESPONSE: The new contracts will be built on DOD policy and will require military treatment facilities to have a contract with whatever pharmaceutical return goods (reverse distribution) it utilizes.

Pharmacy-Owned Drug Reverse Distribution Process (MACRO)

US Air Force Medical Service

2/18/2004

DRAFT



Department of the Navy Comments

Final Report
Reference



DEPARTMENT OF THE NAVY
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20350-1000

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE INSPECTOR GENERAL

SUBJECT: Department of Defense Inspector General (DODIG) Draft Report on DOD Management of Pharmaceutical Inventory And Processing of Returned Pharmaceuticals (Project No. D2003LP-0109) - INFORMATION MEMORANDUM

Per Attachments 1 and 2, the Bureau of Medicine and Surgery (BUMED) comments to the DODIG subject draft report are provided in Attachment 3.

Should you have any questions, please call Mr. Rick Barnish at (202) 762-3336 or email JRBarnish@us.med.navy.mil.

A handwritten signature in black ink, appearing to read "H. L. Cowan".

H. L. COWAN
Surgeon General of the Navy

Attachments:

1. NAVINGEN email tasker of 9 Mar 04
2. DODIG memorandum of 1 Mar 04 with Draft Report
3. BUMED Comments on Draft Report

Omitted
Omitted

BUMED Response to DODIG Draft Report (D2003LF-0109)

Recommendations

A.1. We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Department Surgeons General, develop policy and procedures that:

a. Require the military treatment facilities to:

(1) Establish stock levels based on facility workload, scope and level of care, and mission.

(2) Require the facility to validate the stock levels on a periodic basis.

b. Standardize the criteria for identifying expiring pharmaceuticals and removing those pharmaceuticals from inventory.

c. Establish standard procedures for stocking pharmaceuticals on the shelves to ensure those with the earliest expiration date are dispensed first.

d. Establish oversight procedures to ensure the policy and procedures are implemented and followed.

BUMED Response: Concur

A.2. We recommend that the Assistant Secretary of Defense (Health Affairs) ensure the upgraded pharmacy component of the Composite Health Care System II:

a. Interfaces with the Defense Medical Logistics Standard Support system for automatic ordering.

b. Incorporates a capability to automatically identify expiring or expired pharmaceuticals, when expiration date information is embedded in pharmaceutical product labels.

BUMED Response: Concur with comments

Comment: The Department of Defense is currently evaluating a commercial-off-the-shelf Pharmacy package, to be interoperable with CHCS-II, as a replacement for the legacy pharmacy capabilities within CHCS. An integrated supply management capability is a requirement for this solicitation, enabling

BUMED Response to DODIG Draft Report (D2003LP-0109)

pharmacy to track ordering, receipt of product, to final dispensing to patient. Recommend that the services collectively establish standard business rules to leverage the capability of this system, along with monitoring parameters, and metrics that can be reviewed at the local level for action, as well as consolidated for upward reporting for service oversight.

B.1. We recommend that the Military Department Surgeons General direct military treatment facilities to either use the Pharmaceutical Returns Management Program contractor or have valid authorization for procuring and paying for the services received from another pharmaceutical returns company.

BUMED Response: Concur

B.2. We recommend that the Commander, Defense Supply Center Philadelphia:

a. Modify the pharmaceutical prime vendor contracts to:

(1) Allow for payments to pharmaceutical returns companies other than the Pharmaceutical Returns Management Program contractor.

(2) Allow the prime vendors to make payments to pharmaceutical returns companies only after verifying that a contract exists between the military treatment facility and the pharmaceutical returns company. If there is no contract, direct the prime vendors not to make payments from the military treatment facilities' credit accounts.

b. Provide oversight of the current Pharmaceutical Returns Management Program contract to ensure that the contractor provides the services and reports required by the contract.

BUMED Response: Concur

B.3. We recommend that the Military Department Surgeons General develop policy and establish oversight procedures to ensure that military treatment facility pharmacy or medical logistics staff:

a. Ensure an inventory of all returned pharmaceuticals is prepared or generated before the shipment leaves the facility.

BUMED Response to DODIG Draft Report (D2003LF-0109)

b. Track the costs associated with their pharmaceutical returns services and the amount of credits to ensure the costs for the services provided are reasonable and the credits received are complete.

c. Analyze returned pharmaceuticals data for trends that indicate a need to modify inventory levels or ordering practices.

BUMED Response: Concur

B.4. We recommend that the Assistant Secretary of Defense (Health Affairs) request that the Department of Veterans Affairs include the following provisions in future contracts for pharmaceutical returns services:

a. Payment to the contractor will not be made until the credits are received and will be based on the actual credits received.

b. A contractor representative will provide on-site services, whenever possible, and the contractor representative will provide an inventory of all pharmaceuticals collected at the facility before they are boxed for shipment.

c. The contractor will produce reports that will allow the pharmacy or logistics staff to track expired pharmaceuticals eligible for credit from collection to receipt of actual credits. The reports will, at a minimum, include information identifying returnable pharmaceuticals with estimated credits, non-returnable pharmaceuticals with the cost for disposal, actual credits received, and contractor fees for each collection of pharmaceuticals.

BUMED Response: Concur

B.5. We recommend that the Assistant Secretary of Defense (Health Affairs) and the Military Departments require the military treatment facilities to use a pharmaceutical returns company that receives a contract when the next procurement for services is awarded.

BUMED Response: Concur

Status: Open

Department of the Air Force Comments



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

MAY 21 2004

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL FOR AUDITING OFFICE OF
THE INSPECTOR GENERAL DEPARTMENT OF DEFENSE

FROM: HQ USAF/SG
1420 Air Force Pentagon
Washington DC 20332-1420

SUBJECT: Draft Audit Report on DoD Management of Pharmaceutical Inventory and
Processing of Returned Pharmaceuticals March 1, 2004, Project No. D2003LF-0109

This is in reply to your memorandum requesting the Assistant Secretary of the Air Force (Financial Management and Comptroller) to provide Air Force comments on subject report. I agree with the concept of this memorandum.

AF pharmacy and medical logistics have been working with the AF Audit Agency, DSCP and the DOD Pharmaceutical Reverse Distribution Working Group to develop AF criteria for pharmaceutical inventory management. The findings of this DOD audit support the guidance and programs we are currently developing. Detailed comments on the recommendations are attached.

I appreciate the opportunity to review the proposed memorandum and offer my comments. My point of contact is Col Ardis Meier at (240) 857-2848, DSN 857-2848 or e-mail ardis.meier@pentagon.af.mil.

A handwritten signature in black ink, appearing to read "G. Peach Taylor, Jr.", written over a white background.

GEORGE PEACH TAYLOR, JR.
Lieutenant General, USAF, MC, CFS
Surgeon General

Attachments:
As stated

INSPECTOR GENERAL, DEPARTMENT OF DEFENSE (IG, DoD) DRAFT REPORT
MARCH 1, 2004 (PROJECT NO. D2003LF-0109)

REPORT ON DOD MANAGEMENT OF PHARMACEUTICAL INVENTORY AND
PROCESSING OF RETURNED PHARMACEUTICALS

DEPARTMENT OF THE AIR FORCE COMMENTS
TO THE IG, DOD RECOMMENDATIONS

RECOMMENDATION A.1.: We recommend that the Assistant Secretary of Defense (Health Affairs), in coordination with the Military Department Surgeons General, develop policy and procedures that:

a. Require the military treatment facilities to:

- (1) Establish stock levels based on facility workload, scope, level of care, and mission.
- (2) Require the facility to validate the stock levels on a periodic basis.

b. Standardize the criteria for identifying the expiring pharmaceuticals and removing those pharmaceuticals from inventory.

c. Establish standard procedures for stocking pharmaceuticals on the shelves to ensure those with the earliest expiration date are dispensed first.

d. Establish oversight procedures to ensure the policy and procedures are implemented and follow.

AF RESPONSE: Concur. AF requested the AF Audit Agency to complete an extensive audit of AF pharmacy inventory management and control in July 2002. The initial planning audits began in August 2002. The AF agency began inspection of 17 AF pharmacies in February 2004. Initial findings from the AF Audit Agency are similar to this audit. Upon receiving a final report from the AF Audit Agency, AF pharmacy and AF medical logistics proceed with implementation of an automated solution to the recommendations.

RECOMMENDATION A.2.: We recommend that the Assistant Secretary of Defense (Health Affairs) ensure the upgraded pharmacy component of the Composite Health Care System II:

a. Interfaces with the Defense Medical Logistics Standard Support system for automatic ordering.

b. Incorporates a capability to automatically identify expiring or expired pharmaceutical, when expiration date information is embedded in pharmaceutical product labels.

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DOD Draft Report
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AF RESPONSE: Concur. The AF supports an automated solution for pharmacy inventory control. The new pharmacy module for CHCS should accomplish this function.

RECOMMENDATION B.1.: We recommend that the Military Department Surgeons General direct military treatment facilities to either use the Pharmaceutical Returns Management Program contractor or have valid authorization for procuring and paying for services received from another pharmaceutical returns company.

AF RESPONSE: Concur. AF Medical Logistics alerted medical logistics accounts of this issue in its February newsletter. AF Medical Logistics will assist medical logistics accounts in preparing statements of work and engaging with contracting offices to obtain a smooth transition from service agreements to contracts. AF Medical Logistics will engage with reverse distribution vendors in a consultative role to overcome any potential breaks in service or accountability chains.

RECOMMENDATION B.2.: We recommend that the Commander, Defense Supply Center Philadelphia:

a. Modify the pharmaceutical prime vendor contracts to:

(1) Allow for payments to pharmaceutical returns companies other than the Pharmaceutical Returns Management Program contractor.

(2) Allow the prime vendors to make payments to pharmaceutical returns companies only after verifying that a contract exists between the military treatment facility and the pharmaceutical returns company. If there is no contract, direct the prime vendors not to make payments from the military treatment facilities' credit accounts.

b. Provide oversight of the current Pharmaceutical Returns Management Program contract to ensure that the contractor provides the services and reports by the contract.

AF RESPONSE: Concur. The AF assigned a pharmacist to the DMLSS and AF Pharmaceutical Reverse Distribution Working Group (later became DoD) in September 2002. These working groups have been working with Defense Supply Center Philadelphia (DSCP) to ensure implementation of the correct oversight for pharmaceutical contracts. All the services' pharmacy consultants met with DSCP on 6 November 2003 to discuss requirements for new pharmaceutical returns contracts. They will continue to work with DSCP to ensure future contracts include all necessary requirements.

RECOMMENDATION B.3.: We recommend that the Military Department Surgeons General develop policy and establish oversight procedures to ensure that military treatment facility pharmacy or medical logistics staff:

a. Ensure an inventory of all returned pharmaceuticals is prepared or generated before the shipment leaves the facility.

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b. Track the costs associated with their pharmaceutical returns services and the amount of credits to ensure the costs for the services provided are reasonable and the credits received are complete.

c. Analyze returned pharmaceuticals data for trends that indicate a need to modify inventory levels or ordering practices.

AF RESPONSE: Concur. The DOD Pharmaceutical Reverse Distribution Working Group has developed a draft plan, currently in coordination among the services that fully concurs and will satisfy the intent of this recommendation. A flow chart of the proposed (DRAFT) process is attached to this document. A government-supervised 100% inventory will be completed before the vendor leaves the facility. Quarterly credit statements will be reconciled with a baseline inventory for one year; and, after a year, if the estimated credits have not arrived, MTFs will contact vendor to resolve or explain. The working group is still determining the appropriate percentage of estimated credits to be used based on rational explanation of what industry can accommodate. While the working group has yet to discuss specifics of the content of vendor-provided reports, the intended use of a vendor-provided report would be to seek ways to improve inventory and process efficiency. Policy to be generated by this working group will include guidance on use of vendor-provided reports.

RECOMMENDATION B.4.: We recommend that the Assistant Secretary of Defense (Health Affairs) request that the Department of Veterans Affairs include the following provisions in future contracts for pharmaceutical returns services:

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AF RESPONSE: Concur

RECOMMENDATION B.5.: We recommend that the Assistant Secretary of Defense (Health Affairs) and the Military Departments require the military treatment facilities to use a pharmaceutical returns company that receives a contract when the next procurement for services is awarded.

AF RESPONSE: The new contracts will be built on DOD policy. There should be no reason to use any other contracts.

Enclosure to Letter
DOD Draft Report
Page 3 of 3

Team Members

The Office of the Deputy Inspector General for Auditing of the Department of Defense, Readiness and Logistics Support prepared this report. Personnel of the Office of the Inspector General of the Department of Defense who contributed to the report are listed below.

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