Healthcare Inspection

Pharmacy and Quality of Care Issues
VA Hudson Valley Health Care System
Castle Point, New York
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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted a review to determine the validity of a complainant’s allegations related to chemotherapy services, pharmacy inventory management, physician hiring practices, pharmacy staffing, and pharmacy work environment at the Castle Point Campus of the VA Hudson Valley Health Care System (facility) in Castle Point, NY.

We did not substantiate that patients receiving chemotherapy died in the chemotherapy clinic or while being transferred to community hospitals for stabilization due to limited care at the facility. We found the level of care to be adequate and that one patient death two years ago was unrelated to the quality of care provided at the clinic. We did substantiate that there were issues with timeliness of chemotherapy treatment due to the location of a chemotherapy hood used to prepare chemotherapy compounds.

We presented findings to the Director about deceptive pharmacy inventory management practices, which resulted in the appointment of an Administrative Investigation Board (AIB). The AIB concluded that pharmacy staff, at the direction of pharmacy management, intentionally understated the value of pharmacy inventory, and recommended changes to inventory and fiscal management processes to bring them into compliance with VA directives. We concurred with the findings and recommendations of the AIB.

We substantiated the allegations that pharmacy staff, at the direction of management, removed approximately $500,000 of chemotherapy and other drugs before the annual physical inventory count in February 2012. Pharmaceutical supplies were moved to the basement to exclude them from the inventory count. We did not substantiate that pharmaceutical supplies were not returned to the pharmacy, or that chemotherapy drugs were hidden in the basement and unused. We substantiated that there were drug shortages caused by an inadequate inventory management system and a national shortage resulting in back-orders.

We did not substantiate allegations related to physician hiring, safety issues for pharmacy staff who worked alone, or a pharmacy manager’s conduct. The allegation regarding non-compliance with EEO policy is outside the scope of our authority and was referred to the HVHCS Human Resources department.

We recommended that the Director follow the recommendations of the Administrative Investigation Board, and additionally, provide ethics training for pharmacy staff and a means to report unethical behavior without fear of repercussion.

The Veterans Integrated Service Network and Facility Directors concurred with the recommendation and provided an acceptable action plan. We will follow up on the planned actions until they are completed.
TO: Director, VA NY/NJ Veterans Healthcare Network (10N3)

SUBJECT: Healthcare Inspection – Pharmacy and Quality of Care Issues, Castle Point Campus, Castle Point, New York

Purpose

The VA Office of Inspector General Office of Healthcare Inspections conducted a review to determine the validity of a complainant’s allegations related to chemotherapy services, pharmacy inventory management, physician hiring practices, pharmacy staffing, and pharmacy work environment, at the Castle Point Campus (facility) of the VA Hudson Valley Health Care System (HVHCS) in Castle Point, NY.

Background

Hudson Valley Health Care System-Castle Point Campus

The facility is located in Dutchess County, NY, on the banks of the Hudson River and just 65 miles north of New York City. It is a primary and secondary health care facility, delivering modern, progressive health care services to veterans of the Hudson Valley. The facility provides a wide range of medical services, intermediate medicine, rehabilitation medicine, and spinal cord injury care. HVHCS is part of Veterans Integrated Service Network (VISN) 3.

Chemotherapy

Chemotherapy refers to the use of special medications for cancer treatment. The American Cancer Association reported that there are over 100 chemotherapeutic medications, and they are often used in combination with other medications and treatments, such as surgery or radiation. Depending on the patient and the type and stage of cancer, the chemotherapy may be given orally or intravenously (into the patient’s vein), as an inpatient or an outpatient treatment. Intravenous treatments may be given over the course of several hours.

To prevent serious complications or death from infection, blood clots, and other problems, chemotherapy equipment and preparations must be free of contaminants, such as bacteria, dust, and other air or surface borne materials. The Veterans Health Administration (VHA) requires that pharmacies comply with United States Pharmacopeia (USP) 797, which mandates procedures and processes for sterile drug compounding (mixing) of pharmaceuticals in a clean room environment. A clean room is a specially designed space that is sealed and pressurized to control airflow. Special cabinets (referred to as “hoods”) are used in clean rooms to further filter the air and maintain sterile conditions. Workers must wear gowns, gloves, and other protective gear while working in clean rooms.

The design of the clean room also serves to reduce employee exposure to these hazardous drugs. Tiny amounts of chemotherapeutic chemicals can cling to packaging materials, spray into the air during mixing, and release in other ways during handling. Studies have shown that over time, such micro-exposures may have a cumulative effect and result in negative consequences for the workers who handle them, including higher rates of cancer, infertility, and other reactions. Therefore, facilities are advised to implement safety programs and measures to prevent contamination wherever hazardous drugs are received, stored, prepared, administered, or disposed of.

Professional organizations, such as the American Society of Health-System Pharmacists, have published guidelines to address chemotherapy safety. These guidelines require that chemotherapies be prepared: (1) in specific, ventilated cabinets with hoods; (2) away from patients, staff, and visitors; and (3) with defined steps and devices to minimize release of the medication into the environment. Likewise, the chemotherapy medication and materials that are exposed to it must be treated as hazardous drug waste and disposed of properly.

**Pharmacy Operations**

Pharmacy operations were moved to a new location in the facility in 2011. Previously, pharmacy operations were located in the basement of the facility. This area is still being used to store drugs and prepare chemotherapy compounds due to unresolved ventilation issues in the new location.

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2. [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm) [accessed 9/19/2012]
Pharmacy Inventory Management

Administrative Investigation Board

On May 23, 2012, OIG presented information to the HVHCS Director that pharmacy management and staff were complicit in or aware of steps that were taken to intentionally understate the value of pharmacy inventory in February 2012 as well as in prior years. The Director concluded that an Administrative Investigation Board (AIB) was appropriate to investigate the allegations regarding pharmacy inventory management. The AIB convened on June 14, and conducted site visits, obtained sworn testimony from HVHCS employees, and reviewed relevant material in arriving at their findings of fact, conclusions, and recommendations. Their report was made available to the OIG on August 31, 2012.

Significant conclusions reached by the AIB are as follows:

- Before the wall-to-wall inventory each year, excess inventory is relocated within the pharmacy to areas that are not inventoried. This practice resulted in the FY2012 inventory discrepancy of approximately $500,000.

- There is a routine practice of the Pharmacy Program receiving additional funds in the last quarter of the fiscal year to purchase medications.

- Sporadic excessive funding for medication purchases results in an overstock situation, which can negatively impact the pharmacy inventory turnover. This funding method prevents the use of proper inventory management procedures.

- There are large quantities of chemotherapy medications located in the basement pharmacy. These medications are not hidden, but are located in locked refrigerators. Since these medications are accounted for, diversion is unlikely.

- Shortages of medications that occur are generally due to common pharmacy supply issues.

- The process for the destruction/disposal of expired medications follows recommended guidelines.

AIB recommendations included consideration of appropriate administrative action, training in inventory management in compliance with VHA guidelines, and better fiscal management of pharmacy funds.

We reviewed the AIB report and concurred with their findings and recommendations.

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7AIB (#43), Report of Investigation into the aspects of pharmacy management and inventory control processes, August 9, 2012
We have incorporated only the AIB findings that are within the scope of our review in this report.

**VHA Inventory Guidelines**

VHA requires\(^8\) that an annual wall-to-wall physical count of inventory be completed by February 28\(^{th}\) of each year. Annual inventory results must include a description of each drug product, the measured on-hand quantity, and the estimated value. These inventory counts are required to maintain accuracy and ensure appropriateness of the items kept in stock. The directive states that Pharmacy Benefits Management (PBM) collects the wall-to-wall inventory data nationally and prepares a report that goes to the VISN and VHA Procurement and Logistics Office.

The primary measure of effective inventory management is turnover. It is defined as the number of times an item is replaced within an inventory in a designated period from replenishment to consumption. VHA’s benchmark for turnover is 12 or higher. Low turnover indicates poor inventory management and typically means the product has been sitting on the shelves for too long. Overstocking of shelves increases the risk of expiration, contamination, or obsolescence of inventory, and is an inefficient use of VHA resources.

Furthermore, VHA Pharmacy Inventory Guidelines\(^9\) provide specific instructions on the annual inventory process to ensure the accuracy of the ending inventory and include the requirements to:

- Count all drugs with an inventory valuation greater than $500
- Randomly verify inventory counts

**Allegations**

In March 2012, a complainant contacted VA’s OIG Hotline Division and alleged that:

**Issue 1: Chemotherapy Services**

- Patients have died in the chemotherapy clinic because the facility lacks an intensive care unit and patients have to be moved to other hospitals for stabilization.
- Chemotherapy patients do not receive their treatments timely even though they are prepared timely by the pharmacist.

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\(^8\) VHA Handbook 1761.02, *VHA Inventory Management*, October 20, 2009

\(^9\) VHA Pharmacy Inventory Guidelines, *Wall to Wall Inventory Instructions*, 2009
• Chemotherapy drugs are mixed in a chemotherapy hood that fails lab tests almost every other month while a new chemotherapy hood sits unused in the basement.

Issue 2: Pharmacy Inventory Management

• Pharmaceutical supplies worth hundreds of thousands of dollars were removed from the pharmacy and hidden by pharmacy managers before the annual outside inventory and very few of the supplies are returned.

• Chemotherapy drugs worth thousands of dollars are stored in the basement pharmacy and sit unused and hidden by managers.

• Pharmaceutical supplies are always short.

Issue 3: Physician-Hiring Practices

• Talented physicians hired on a temporary appointment are leaving HVHCS after one or two years because they are unable to secure permanent employment.

Issue 4: Pharmacy Staffing

• One pharmacist remains on duty until midnight alone without any technical support or security.

Issue 5: Pharmacy Work Environment

• The work environment in pharmacy is toxic due to rude, unprofessional behavior of a pharmacy manager, which impedes the discussion of patient care. Complaints to pharmacy leadership have gone unresolved.

Issue 6: Non-compliance with EEO policy

• The complainant further alleged that employees of the HVHCS are discriminated against due to their race, gender, sexual orientation, and religion.

This issue is outside the scope of our authority to review and was referred to the HVHCS Human Resources (HR) department for investigation.

Scope and Methodology

We conducted a site visit from May 21 through May 23, 2012. We interviewed the HVHCS Director; staff from engineering, chemotherapy, pharmacy, human resources, VISN 3 Pharmacy Benefits Management; and other staff knowledgeable about the issues. Additionally, we interviewed staff employed by the company contracted to perform the physical inventory of pharmaceutical drugs. We reviewed documents regarding electronic health records (EHR), chemotherapy hood lab inspection reports, personnel
records, pharmaceutical inventory reports, inventory analyses, purchases, and other relevant documents. We reviewed relevant VHA directives, as well as HVHCS policies and procedures. Additionally, we reviewed the results from the AIB regarding pharmacy inventory management.

We did not investigate the allegation regarding discrimination. This allegation was referred to the HVHCS HR department to investigate.

We conducted the inspection in accordance with Quality Standards for Inspection and Evaluation published by the Council of the Inspectors General on Integrity and Efficiency.

**Inspection Results**

**Issue 1: Chemotherapy Services**

**Patient Death**

We did not substantiate that patients receiving chemotherapy died in the chemotherapy clinic or while being transferred to community hospitals for stabilization.

Patients receiving chemotherapy can become ill with nausea and other symptoms related to the type of chemotherapy delivered or underlying disease process(es). Over the past 2 years, one patient transferred out of the medical center on the day that he received chemotherapy and later died. HVHCS had completed a root cause analysis (RCA).

We reviewed the subject patient’s EHR and agreed with the RCA conclusion. During interviews, the chemotherapy staff reported that the needs of patients vary, and the facility’s urgent care and acute services are appropriate to meet these needs.

**Timeliness of Care**

We substantiated that there are issues with chemotherapy timeliness.

The chemotherapy pharmacy is housed in a separate location from both the chemotherapy clinic and the main pharmacy. There is one pharmacist located within the chemotherapy pharmacy who prepares all orders, and a second pharmacist who comes from the main pharmacy to the chemotherapy pharmacy to validate the physician’s orders and check the preparation for accuracy. Once the order is completed, a technician is called and asked to deliver the order from the chemotherapy pharmacy to the chemotherapy clinic. There are

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inherent delays that occur in waiting for these other team members to come to the chemotherapy pharmacy when called.

In 2009, a systems redesign project was initiated to specifically address the issues of chemotherapy timeliness. In 2011, and as a result of this project, the facility opened a new pharmacy located near the outpatient clinics and purchased a new chemotherapy hood. Due to unresolvable engineering issues, the chemotherapy hood could not be installed in the new chemotherapy pharmacy and problems with airflow in the new pharmacy prevented immediate relocation of the “old” chemotherapy hood. A facility engineer projected that the airflow problem would be corrected by January 5, 2013, and the “new” chemotherapy hood would be relocated to the new pharmacy shortly thereafter. Once complete, wait times should decrease significantly.

The staff seems conscientious and concerned about the matter of timeliness and we found no complaints from patients receiving chemotherapy or the patient advocate.

Chemotherapy Hood

We did not substantiate that the chemotherapy hood currently in use failed inspections.

The facility’s chemotherapy hood is tested quarterly by pharmacy staff and every 6 months by an outside independent certification agency. If the hood tests positive for bacteria growth during quarterly testing, the hood is cleaned and retested by pharmacy staff. Any positive retests are reported to Biomedical engineering staff for further correction; however, we found that no positive tests have been reported. During biannual testing, an outside independent certification agency noted an airflow problem which facility engineers corrected by installing a new motor and air filter. Otherwise, we found the 2011 and 2012 external inspection reports indicated that the equipment passed all tests.

Issue 2: Pharmacy Inventory Management

Pharmaceutical Supplies Are Removed and Hidden

We substantiated and the AIB confirmed the allegation that pharmaceutical supplies worth hundreds of thousands of dollars were removed at the direction of pharmacy managers before the external inventory inspection. Pharmaceutical supplies were intentionally excluded from the inventory count.

Pharmacy management directed pharmacy staff to remove chemotherapy and other drugs to a basement location prior to the annual inventory in 2012 and also in prior years. The intent of this removal was to understate the valuation of pharmacy inventory to avoid perceived inventory mismanagement issues. This resulted in understating the inventory by $506,000, which was 41 percent of the actual inventory of $1,246,000.

**Return of Pharmaceutical Supplies**

We did not substantiate the allegation that very few of the pharmaceutical supplies were returned to the pharmacy.

Testimony in the AIB by pharmacy staff and a pharmacy manager confirmed that inventory from the basement is returned to the pharmacy. The basement inventory is used to replenish pharmacy supplies and chemotherapy drugs, as well as to prepare chemotherapy compounds.

**Chemotherapy Drugs – Unused and Hidden**

We did not substantiate the allegation that chemotherapy drugs were sitting unused and hidden in the basement.

We observed that chemotherapy drugs are located in the basement refrigerators near the chemotherapy hood where they are mixed for use. Pharmacy staff verified that the chemotherapy drugs located in the basement refrigerator are used to treat chemotherapy patients and are located in a secure, highly visible area of the basement. Furthermore, the AIB reviewed chemotherapy purchases and found them to be consistent with usage records.

**Pharmaceutical Supply Shortages**

We substantiated the allegation that there are shortages of some pharmaceutical supplies caused by an inefficient inventory management system for non-controlled drugs and delays in obtaining certain drugs from manufacturers.

Drug shortages are attributable to an inefficient and inadequate manual system used to track shortages of non-controlled drugs. Staff interviews and AIB testimony revealed that this manual system requires a pharmacist to write a request in a notebook to order drugs if he or she notices that supplies are running low. If a pharmacist forgets to record an item, delays occur. Pharmacy technologists consolidate drug orders from the notebook and place the order. Pharmacy staff do not receive notification regarding the order placement, quantity ordered, or expected delivery date. This leads to frustration and uncertainty regarding the status of drug requests. Drug shortages can affect patients by prolonging the wait time or by forcing them to seek alternative drug options.
A pharmacy manager stated that drug shortages are also caused by national shortages. Pharmacy staff maintain a whiteboard to identify drugs which are currently unavailable and on backorder.

**Issue 3: Physician Hiring Practices**

We did not substantiate that HVHCS hiring under temporary appointments resulted in the loss of excellent physicians.

Under the authority of 38 U.S.C. §7405(a) (1), facilities may hire temporary physician staff and later convert them to permanent status. The temporary employment offers several advantages, including the:

- Ability to respond to changing veterans’ program needs
- Flexibility for facilities to restructure programs and redirect funding and staffing, when necessary
- Opportunity for both employee and facility to ensure a good “fit”

The complainant did not provide specific examples to support this allegation. The Chief of Staff told us that for several years, HVHCS supplemented their permanent staff by hiring temporary and consultant physicians (including oncologists). However, VISN 3 recently conducted a review and recommended limiting the use of temporary staff in favor of hiring permanent staff. Since then, HVHCS has taken steps to convert most of the temporary positions to permanent appointments.

The HVHCS HR department did not receive any exit conference responses from temporary physicians when they left their positions. We reviewed recent employee satisfaction surveys and patient advocate reports for any complaints related to temporary appointments and found none.

**Issue 4: Pharmacy Staffing**

We did not substantiate that any problems were caused by scheduling only one pharmacist to be on duty during the last hour before pharmacy closing. The pharmacy is open 7 days a week from 8:00 a.m.– midnight. For the past year, one pharmacist was on duty between 11:00 p.m. and midnight. When the facility pharmacy is closed, the NY Harbor Healthcare System provides virtual pharmacy coverage. We spoke with the two pharmacists who work alone between 11:00 p.m. and midnight, and neither expressed concerns about their hours or safety when leaving. We also reviewed facility safety and police reports and did not find any issues related to this schedule.

**Issue 5: Pharmacy Work Environment**

We did not substantiate that the unprofessional behavior of a pharmacy manager negatively impacted discussion about patient care in the pharmacy or that complaints to pharmacy leadership were left unresolved. We found a record of one complaint that was appropriately resolved two years ago, and interviews with pharmacy leadership and staff revealed one recent instance of unprofessional behavior, which was immediately addressed by pharmacy leadership. Review of the most recent personnel evaluations contained no evidence of unprofessional behavior.

**Conclusions**

We determined that the allegations involving the deaths of chemotherapy patients due to inadequate care or during transfers to community hospitals were not substantiated. Over the last two years, there was one instance of a chemotherapy patient becoming sick and requiring stabilization at a local hospital. This patient later died, but the cause was found to be unrelated to the care provided at the facility. We did find that the location of the chemotherapy hood affected the timely delivery of the prepared drug treatments; however, we found no incidents or complaints related to timeliness. Installation of the new chemotherapy hood in the main pharmacy is projected to be completed in January 2013, which will improve timeliness of care for chemotherapy patients.

We did not substantiate the safety issues related to the chemotherapy hood and pharmacy staff working alone at night. The chemotherapy hood was being tested by pharmacy staff on a quarterly basis and every 6 months by an independent certification agency with no reported failures. Our interviews with staff that worked on the late shift did not reveal any concerns and security reported no incidents.

We determined that there was a culture where some pharmacy managers and staff were complicit in or had knowledge of deceptive inventory management practices with the intent to understate the valuation of pharmacy inventory to avoid perceived inventory mismanagement issues.

We concurred with the findings in the AIB and their action plan, which included the following recommendations:

- Consider appropriate administrative actions
- Reeducate staff on proper annual inventory processes
- Develop a local Standard Operating Procedure for inventory management in accordance with VA Directives
- Establish an inventory monitoring system to properly track medication flow in and out of the pharmacy
• Discontinue the practice of distributing large amounts of funds for the purchase of medications at the end of the fiscal year
• Complete construction of the chemotherapy compounding area in the main pharmacy

Physician hiring practices did not result in the loss of excellent physicians and exiting physicians gave no indication that the temporary nature of the appointment was a reason for leaving. We did not find evidence that the conduct of a pharmacy manager negatively impacted patient care discussions or that instances of unprofessional conduct were unresolved by management.

Recommendations

Recommendation 1. We recommended that the Director ensure that the recommendations in the Administrative Investigation Board report are complied with.

Recommendation 2. We recommended that the Director ensure that all pharmacy staff be provided ethics training to ensure that employees report unethical behavior without fear of repercussion.

Comments

The VISN and Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes A and B, pages 12–14 for the Directors’ comments.) We will follow up on the planned actions until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for Healthcare Inspections
Date: November 28, 2012

From: Michael A. Sabo, Director, VA NY/NJ Veterans Healthcare Network (10N3)

Subject: Healthcare Inspection – Pharmacy and Quality of Care Issues, Castle Point Campus, Castle Point, New York

To: Director, Financial Analysis Division, Office of Healthcare Inspections (54D)

Thru: Director, VHA Management Review Service (VHA 10AR MRS)

Attached please find the Healthcare Inspection – Pharmacy and Quality of Care Issues draft response from the VA Hudson Valley Health Care System.

I have reviewed the draft report for the VA Hudson Valley Health Care System and concur with the findings and recommendations.

Should you have any questions, please do not hesitate to contact Pam Wright, RN MSN, VISN 3 QMO at telephone # 718-741-4134.

Michael A. Sabo, FACHE

Director, VA New York/New Jersey Health Care Network
System Director Comments

Department of Veterans Affairs

Memorandum

Date: November 28, 2012

From: Gerald F. Culliton, Director, VA Hudson Valley Health Care System (620/00)

Subject: Healthcare Inspection – Pharmacy and Quality of Care Issues, Castle Point Campus, Castle Point, New York

To: Director, VA NY/NJ Veterans Healthcare Network (10N3)

I want to express my appreciation to the Office of Inspector General (OIG) Survey Team for their professional and comprehensive Healthcare Inspection – Pharmacy and Quality of Care Issues conducted on May 21–23, 2012.

I have reviewed the findings in the draft report for the VA Hudson Valley Health Care System and concur with the findings and recommendations.

I appreciate the opportunity for this review as an important part of the continuing process to improve the care to our veterans.

Gerald F. Culliton, Director, VA Hudson Valley Health Care System
Director’s Comments
to Office of Inspector General’s Report

The following Director’s comments are submitted in response to the recommendations in the Office of Inspector General’s report:

OIG Recommendations

Recommendation 1. We recommended that the Director ensure that the recommendations included in the Administrative Investigation Board report are complied with.

Concur

Target Completion Date: January 5, 2013

System’s Response:

All recommendations included in the Administrative Investigation Board report have been reviewed with actions developed and assigned to responsible parties for completion. Several actions have been completed. The target date for the last item in the action plan to be completed is January 1, 2013.

Status: Open

Recommendation 2. We recommended that the Director ensure that all pharmacy staff be provided ethics training to ensure that employees report unethical behavior without fear of repercussion.

Concur

Target Completion Date: January 1, 2013

System’s Response:

All pharmacy staff have been scheduled to complete training in Organizational Ethics, Prevention of Workplace Violence/No Fear, and Compliance and Business Integrity Awareness.

Status: Open
## OIG Contact and Staff Acknowledgments

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