Department of Veterans Affairs

Office of Inspector General

OFFICE OF HEALTHCARE INSPECTIONS

INSPECTION OF MULTIPLE ALLEGATIONS OF PHARMACY SERVICE MISMANAGEMENT AND SUBSTANDARD PATIENT CARE VA SAN DIEGO HEALTHCARE SYSTEM SAN DIEGO, CALIFORNIA

REPORT: 9HI-A28-112
DATE: MAY 26, 1999

Office of Inspector General
Washington DC 20420

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Department of Veterans Affairs

Memorandum

Date: May 26, 1999

From: Assistant Inspector General for Healthcare Inspections (54)

Subj: Final Report – Inspection of Multiple Allegations of Pharmacy Service Mismanagement and Substandard Patient Care, VA San Diego Healthcare System, San Diego, CA (Report Number: 9HI-A28-112)

To: Medical Center Director (664/00)

1. Enclosed is the final report of findings and conclusions based on the Office of Healthcare Inspections' (OHI) review of multiple allegations of Pharmacy Service mismanagement and 10 episodes of alleged substandard patient care at the San Diego Healthcare System (SDHS). OHI conducted the inspection at the request of Congressman Bob Filner, and the House Committee on Veterans Affairs.

2. In evaluating these allegations, OHI inspectors interviewed the complainants, patients, medical center employees, and executive managers. A senior Pharmacy manager who is assigned to another Veterans Integrated Service Network consulted with OHI inspectors on Pharmacy Service management issues. We also reviewed an extensive volume of documents and correspondence that were associated with the alleged events.

3. We confirmed that three untoward events and one adverse drug reaction had occurred among the 10 alleged cases of substandard care. We did not substantiate the remaining six cases. SDHS Quality Managers and Executive Managers had identified and thoroughly reviewed each case when it occurred, and instituted appropriate corrective actions. Therefore, we did not make any recommendations. We did not substantiate any of the allegations pertaining to flawed Pharmacy Service management practices, and we did not make any recommendations concerning these issues.

(Original signed by:)
JOHN H. MATHER, M.D.

Enclosure

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PART I
INTRODUCTION

Background

The Department of Veterans Affairs (VA) Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) received a letter from a complainant alleging various wrongdoing at the VA San Diego Healthcare System (SDHS). The complainant alleged:

- Mismanagement of Pharmacy Service;
- Under reporting of Pharmacy Service medication errors;
- Narcotic inventory alterations and medications being found in a trash bag;
- Excessive Pharmacy Service employee resignations;
- Employee misconduct; and
- Ten alleged incidents involving substandard patient care

Scope

OHI inspectors and a consulting pharmacist, from another large VA Medical Center that is located in another Veterans Integrated Service Network (VISN), interviewed the complainant at length, on several occasions, to clarify and better understand the allegations. Our pharmacy consultant evaluated Pharmacy Service operations, toured the pharmacy physical plant, and interviewed more than 30 Pharmacy Service employees. OHI inspectors interviewed inpatients and outpatients to ascertain their perceptions of the quality of care provided by SDHS employees. An OHI inspector also reviewed boards of investigations, focused reviews, narcotic inspections, a tort claim report, and employee satisfaction surveys.

This inspection was conducted in accordance with the Quality Standards for Inspections published by the President's Council on Integrity and Efficiency.

Conclusion

We did not substantiate the allegation that Pharmacy Service is mismanaged. Expenses for pharmaceuticals and supplies are within expected parameters. Pharmacy managers have implemented cost avoidance programs, and pharmacy employees are accepting these initiatives with mixed reactions. The pharmacy is successfully maintaining a 30-minute or less waiting time for patients to pick up prescriptions. However, the pace involved in meeting this objective has contributed to substantial employee stress.

Workload trends show a steady increase in ambulatory care prescription volume. Specifically, prescription inputting has increased by 9 percent, and the number of patients who visit the Ambulatory Care Pharmacy increased from 216 daily in February 1998, to 324 daily in February 1999 (44 percent). Pharmacy managers accommodated the prescription increases by temporarily reassigning pharmacists from the clinics to the Outpatient Pharmacy area. Managers also asked inpatient pharmacists to enter discharge prescriptions into the computer in an effort to ensure equitable workload distribution and ease individual burdens that are associated with workload increases. Pharmacists processed 134,584 30-day prescriptions during the 2-month period from December 1, 1998 to February 4, 1999.

We did not substantiate the allegation that pharmacy employees were not reporting medication errors. Thirty of the 31 Pharmacy Service employees whom we interviewed, are aware of, and asserted that they follow, the medication error reporting policy, and have done so for several years.

We did not substantiate the allegation that pharmacy employees or managers alter narcotic inventories, or that an unknown person placed a quantity of medications in a trash bag in an apparent effort to smuggle the drugs out of the pharmacy. An October 1997 OIG investigation thoroughly evaluated and did not substantiate this allegation.

We did not confirm the allegation that 15 Pharmacy Service employees resigned within a short period of time because of unacceptable working conditions. In 1998, four employees resigned to obtain salary increases, three resigned because of changing family situations, including child care concerns, and three resigned for various other reasons.

We did not substantiate the allegation that one employee engaged in misconduct. SDHS officials denied ever having received any facts or credible information regarding an incident in which a medical center supervisor allegedly walked out of her office with her blouse unbuttoned to speak with a patient.

Inspectors evaluated 10 incidents of alleged untoward patient care. We did not substantiate six of the alleged incidents. Of the remaining four incidents, two involved prescription filling errors, neither of which resulted in adverse consequences for the patients. The third incident involved a 71-year-old man who experienced an adverse drug reaction. We concluded that this incident was not precipitated by a clinical error, but was the result of an unusual reaction to this particular drug combination. In the fourth incident, that occurred about 4 years before our inspection, we substantiated untoward patient care. SDHS Quality Management (QM) employees and

executive managers had identified and thoroughly evaluated all four of the cases at the times that they occurred. The documentation of these four incidents, and the investigations associated with them are complete, and each case has a properly completed Report of Special Incident Involving a Beneficiary (VA Form 10-2633).

PART II
INSPECTION FINDINGS

Facility

The VA SDHS, is a full-spectrum, tertiary care provider. The SDHS has 232 inpatient beds, and operates primary care and specialty outpatient clinics. Forty of the 232-inpatient beds devoted to extended care, 29 beds comprise the Substance Abuse Treatment Program, and 20 beds are assigned as a Spinal Cord Injury Unit. THE SDHS operates a satellite Ambulatory Care Clinic and three Community Based Outpatient Clinics (CBOC). The medical center is adjacent to its affiliated institution, the University of California, San Diego School of Medicine.

OHI conducted an on-site inspection of the complainant's allegations at the SDHS during the week of March 1, through March 4, 1999. The on-site inspection was conducted to assess the validity of several allegations involving Pharmacy Service mismanagement and 10 cases of alleged substandard patient care.

Pharmacy Service Mismanagement

Allegation 1: The complainant alleged that the SDHS Pharmacy Service was being mismanaged.

We did not substantiate this allegation.

Our consulting pharmacist thoroughly evaluated Pharmacy Service business practices and concluded that pharmaceuticals and supply expenses are within expected parameters. Pharmacy Service managers have initiated cost avoidance programs. Pharmacy Service employees have generally accepted the initiatives, but have mixed feelings about the affect that these initiatives have had on them. Our consulting pharmacist found that pharmacy managers have successfully maintained a 30-minute or less patient waiting time to pick up prescriptions. This achievement complies with Veterans Health Administration (VHA) requirements, but has led to the Outpatient Pharmacy being a high-stress work environment that requires employees to walk more from their work stations to other pharmacy areas, and to engage in increased repetitive motion activities. Pharmacists and technicians, whom we interviewed, all feel that they are under enormous stress to meet the 30-minute prescription waiting time requirement, and that meeting the objective has significantly reduced their job satisfaction.

Medical center managers consulted with an industrial consultation service to conduct an ergonomic analysis of Pharmacy Service work area. The consultants recommended multiple changes to the work stations. Managers concurred with the recommendations and are in the process of implementing them. Managers also initiated a Pharmacy Process Improvement Committee to identify problems involving efficiency in the Ambulatory Care Pharmacy Section and to identify and implement solutions. The Committee made several recommendations that have resulted in improved utilization of pharmacists and efficiency of operations.

Medication Errors Under-Reporting

Allegation 2: The complainant alleged that Pharmacy Service employees do not report medication errors, and that this puts patients' lives in jeopardy.

We did not substantiate this allegation.

During our interviews with 31 Pharmacy Service employees, all but 1, were familiar with Pharmacy Service medication error reporting procedures. All of the 30 pharmacy employees could clearly articulate the error reporting expectations and asserted that they have followed established medication error reporting policy for several years. Most of the employees did not perceive that the number of medication errors that occurred was as high as reported. The Pharmacy Service Quality Assurance (QA) Coordinator reported that Pharmacy Service employees committed 36 medication errors during Calendar Year 1998. During the months of January and February 1999, the number of Pharmacy Service medication errors increased to 24 reported errors. This increased Pharmacy Service medication error rate occurred in the Ambulatory Care Pharmacy Section. Managers monitor these errors and identified the following trends:

- During January and February 1999, Pharmacy Service employees reported 24 errors. Eleven of the 24 medication errors occurred when Pharmacy Service employees placed two or more patients' medications into the same packages and dispensed the packages to one of the patients. Pharmacy Service managers implemented an intermediate inspection procedure to decrease this type of error at the pick-up window. The intermediate procedure entails reviewing the medications to ensure that patients receive all medications and other items that their physicians order, and that packages do not contain any medications that do not belong to the patients. Since managers implemented this intermediate step there have not been any similar errors.

- At least 3 of the 24 reported errors were attributable to "filling" error.

- The remaining 10 medication errors occurred because of clerical errors that employees made when they entered prescriptions incorrectly into the pharmacy computer system. Pharmacy Service managers identified one individual who appears to have been responsible for the majority of these "entry" errors. The section supervisor verbally counseled the employee and provided an opportunity for performance improvement.

- Pharmacy employees reported only six medication errors during March 1999, which represents a considerable decrease from previous 2 months.
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Altering Narcotic Inventory and Suspected Medication Diversion in the Trash

Allegation 3: The complainant alleged that an October 1997 OIG investigation was not sufficiently thorough and that certain employees continue to alter narcotic inventories.

We did not substantiate this allegation.

In late fall of 1995 or early 1996, a pharmacy technician who was working in the ***(b)(6)*** Satellite Pharmacy, mistakenly discarded a note in the trash receptacle. As he opened the trash receptacle to retrieve the note, he noticed a brown market bag that contained a trash bag. Upon further examination, he determined that the bag contained a number of pharmaceuticals, such as patients' home medications, some unit dose drugs, and a small quantity of scheduled narcotics. The pharmacy technician reported finding the medications to his supervisor. But, the supervisor allegedly failed to properly follow up on the reported incident.

Similarly, the complainant alleged that several controlled substances were critically short in several of the medical centers' inpatient pharmacy satellites, and that the supervisors, who became aware of the discrepancies, failed to initiate appropriate actions to determine the causes of the shortages.

OIG investigators thoroughly evaluated these allegations in October 1997. An OIG investigation of QA Section, Police and Security Service (Police), and Pharmacy Services records showed that the SDHS maintained an adequate narcotic tracking and monitoring system. OIG investigators also determined that QA Section employees or VA police officers, or both properly examined and resolved the incidents of reportedly missing narcotics.

VA police records show that investigative reports had been prepared in all instances of missing pharmaceuticals. Police officers prepared these reports

whenever someone complained about missing substances, or when a routine or unannounced narcotics inspection identified inventory discrepancies.

During the October 1997 investigation, OIG investigators also assessed the incident in which pharmacy managers allegedly did not follow prescribed procedures when an employee reportedly found a quantity of drugs in a trash can. Investigators discussed their findings in this case with the Assistant United States Attorney (AUSA) for the Southern District of California. The AUSA elected not to pursue the case because the evidence was insufficient to obtain a conviction. The lack of strong evidence that someone had committed a criminal act, combined with the AUSA's decision not to prosecute, led investigators to close the case.

Since the October 1997 OIG investigation medical managers have identified four discrepancies with controlled substances. Quality performance records show that the VA SDHS does not appear to experience an unusually high number of incidents involving missing narcotics, or discrepancies in its regular and/or unannounced drug inventories. The records show that the SDHS has and maintains an adequate narcotic monitoring tracking system.

Employee Misconduct

Allegation 4: The complainant alleged that a *(b)(6)* supervisor was not wearing her blouse when she walked out of her office to speak with a patient.

We did not substantiate this allegation.

SDHS officials denied ever having received any facts or credible information regarding an incident in which a medical center supervisor allegedly walked out of her office with her blouse unbuttoned to speak with a patient. We could not find any records or other evidence to suggest that such an incident ever occurred.

Substandard Patient Care

Allegation 5: The complainant alleged that several SDHS patients are receiving, or have received substandard medical care.

We substantiated that three incidents of untoward patient care occurred. However, SDHS quality managers and executive managers had identified and properly evaluated each incident at the times that it occurred.

In one case clinicians discovered that a 71-year-old man, who had numerous health problems, had an elevated blood cholesterol level. The patient's physician prescribed two medications (simvastatin and gemfibrozil) to lower his cholesterol. On May 5, 1998, because the patient's cholesterol level continued to increase, his physician increased the simvastatin dosage to twice daily. On May 26,1998, the patient contacted his physician because he reportedly had not urinated for about 36 hours. Clinicians dispatched an ambulance to the patient's home, and physicians admitted him to the medical center with a diagnosis of acute renal failure. The patient's hospital course was complicated by sepsis (toxins in the blood), an acute myocardial infarction (heart attack), a pulmonary embolism (a clot blocking an artery), and gastrointestinal bleeding (bleeding from the stomach into the intestines).

On June 22,1998, clinicians found the patient unresponsive in his room. He was pronounced dead. Medical center clinical managers thoroughly reviewed this case ***(b)(3)*** ***(b)(3)*** The Pharmacy and Therapeutics (P&T) Committee also reviewed the adverse reaction. ***(b)(3)*** ***(b)(3)*** . Pharmacy Service managers also added the drug interaction information to the automated warning system in the pharmacy computer package.

(b)(3) We concluded that this incident was not precipitated by clinician error, but was the result of an unusual reaction to this particular drug combination.

One case involved an error in administering cancer chemotherapy medication and culminated in a November 13,1997 Federal Tort Claim Act financial settlement in the U.S. District Court for the Southern District of California ***(b)(6)*** ***(b)(6)***

The patient in this case was a 59-year-old man who was diagnosed, in 1994, as having symptoms of a brain tumor. On December 12,1994, a private physician biopsied the patient's brain, and the pathologic examination revealed an inoperable brain lesion. Private sector oncologists recommended treatment with radiation and chemotherapy. In early 1995, the terminally ill patient began radiation therapy for palliation. The patient completed his radiation therapy on March 31,1995. In early April 1995, clinicians administered a first cycle of chemotherapy to the patient, with the patient's consent. The patient tolerated this initial course of chemotherapy treatment without any apparent complications.

On April 25,1995, the patient was placed in a private sector nursing home because his wife reportedly could not manage him "physically and emotionally". He began exhibiting violent behavior toward the nursing home employees, such as, throwing objects or spitting on the nurses.

On May 16,1995, clinicians transferred the patient from the private nursing home to the SDHS for treatment of a deep vein thrombosis (blood clot). On May 19,1995, while hospitalized at the SDHS he began to yell and demand that clinicians remove his intravenous (IV) line. Clinicians applied soft restraints so that he would not remove his IV.

On May 25, 1995, A neuro-oncology physician at the University of California, San Diego ordered a second cycle of cancer chemotherapy with the fighting medication (CCNU 260mg) (chemotherapy) to be administered to the patient at bedtime. The patient received nine doses of the chemotherapy medication over a 9-day period. The manufacturer's recommended dosage for CCNU is calculated by body surface area with a recommended dosage of 100-130 mg per square meter. The recommended dosage is one dose to be administered every 6 weeks.

On June 5, 1995, the patients' SDHS attending physician became aware of the chemotherapy error and informed the patient's wife. The patient attending physician simultaneously informed the patient's wife that there is an antidote that can reverse the damage caused by the resultant dangerously low white blood cells. The antidote would be comprised of another medication and/or blood transfusions. On June 7, 1995, the patient's wife decided that she did not want physicians to administer the antidote, because the patient was terminally ill. The patient's condition worsened, and on June 13, 1995, he died of an overwhelming infection associated with the low white blood cells. The cause of death was respiratory failure due to brain cancer.

On June 9, 1995, the Medical Center Director initiated a peer review to assess the events and to identify the causes of possible errors in this case. The peer reviewers recommended, and SDHS managers implemented the following actions:

- ***(b)(3)*** .....

- ***(b)(3)***

- ***(b)(3)***

- ***(b)(3)***

- ***(b)(3)***

Our inspection confirmed that SDHS managers implemented thorough guidelines for ordering and safely handling the administration of chemotherapy agents used in the treatment of malignant and non-malignant diseases. Since the implementation of this policy and associated procedures, there have been no further similar incidents involving chemotherapy.

During the local peer review of the issues in this case, ***(b)(3)*** ***(b)(3)*** ***(b)(3)*** Therefore, the Chief of Pharmacy Service ***(b)(6)*** who were assigned to the patient care area, and were responsible for drug distribution activities during the entire time that the patient received this medication. The OIG's forensic document examiner evaluated the document in question and was not able to obtain the original signature.

Two Allegations Involved Pharmacist Prescription Filling Errors.

On August 5,1998, a physician wrote a prescription for glyburide 5 mg (glucose lowering medication). OHI inspectors learned that the pharmacy clerk entered the prescription correctly in to the computer. However, the responsible pharmacist dispensed glypizide (also a glucose lowering medication) to the patient without any apparent adverse event occurring. Employees properly reported this error and managers reviewed it in order to reduce the possibility that it would reoccur.

In another case that involved a dispensing error, a pharmacist dispensed the wrong medication dosage. A pharmacist dispensed a stavudine prescription

incorrectly to a patient who had human immune-deficiency virus (HIV). The physician had ordered the patient to take the medication at a dose of 20 mg per day, but the pharmacist gave the patient 40 mg tablets. We did not identify any process problems associated with this dispensing error. Rather, the error appears to have been caused by the dispensing pharmacist's carelessness. The patient did not experience any adverse consequences as a result of this medication error. Employees reported the error and managers properly reviewed the circumstances associated with it.

Allegation 6: The complainant alleged that a patient had to wait 5 hours to obtain medication.

We did not substantiate this allegation because the complainant did not provide any verifiable information about the incident.

Allegation 7: The complainant alleged that an inpatient was having seizures, and that the nurses were angry because they had reportedly tried unsuccessfully to call the Inpatient Pharmacy Section for nearly 5 hours to obtain an anti-anxiety medication (Librium ®).

We did not substantiate this allegation.

A pharmacist was allegedly informed to obtain the medication and take it immediately to the nursing unit. The complainant recalled that the patient was in renal failure and required mannitol as a diuretic. The complainant could not provide any further information pertaining to this case, and inspectors could not elicit any information from other employees, or in medical center records, about this or any similar incidents.

Allegation 8: The complainant alleged that a physician improperly infused Cyclosporin®, an immunosuppressive, too quickly.

We did not substantiate this allegation. The event occurred but the rapid infusion was not improper.

The physician administered an entire dose of Cyclosporin®, within a 30-minute period, to a patient in the Medical Intensive Care Unit (MICU). The MICU pharmacy employee felt that the 30-minute Cyclosporin® infusion was acceptable. The MICU pharmacist asserted that the literature does not contain any information that prohibits a short infusion time. One pharmacist disagreed with the infusion time and argued that Cyclosporin® should be

infused over a 6-hour period of time. The Chief of Pharmacy contacted the pharmaceutical corporation that manufactures the Cyclosporin®. Pharmaceutical corporation officials responded, in writing, that there have been cases in which clinicians have infused an entire daily Cyclosporin® dose in 30 minutes. The patient's medical record shows that he did not experience any adverse consequences as a result of the accelerated infusion rate.

Two Final Cases Involved Patients Who Alleged that They Could Not Obtain Initial Primary Care Appointments Quickly Enough

In OHI's opinion, both of these patients had sufficient cause for irritation, because they had to wait for long periods of time from the times that they applied for non-urgent treatment until they were seen by physicians. Medical center managers were aware of the lengthy waiting times that some patients were experiencing to obtain initial appointments and are taking appropriate actions to reduce these waiting times.

One patient whom we interviewed in December 1998, complained that it took too long to see a primary care physician. The patient recalled that when he presented to the medical center an employee told him that it would be 4 to 6 months before he could obtain an appointment to see a physician. A physician saw the patient on March 19,1999, in the Firm Clinic (primary care clinic) and is scheduled to have a return appointment on June 18, 1999.

Another patient complained to inspectors, in December 1998, that he had been trying unsuccessfully to obtain an appointment in the Firm Clinic since November 3, 1998. This patient was seen in the Firm Clinic on February 9, 1999. He has a scheduled follow-up appointment on August 10, 1999.

Since medical center managers had identified and reviewed the individual patient care issues that complainants presented, and since they had initiated reasonable actions to correct practices or circumstances that led to the incidents occurrence, we did not make any recommendations.

PART III
RECOMMENDATIONS

We did not make any recommendations.

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