



**Department of Veterans Affairs
Office of Inspector General**

**Combined Assessment Program
Review of the
VA Medical Center
Minneapolis, Minnesota**

Office of Inspector General Combined Assessment Program Reviews

Combined Assessment Program (CAP) reviews are part of the Office of Inspector General's (OIG's) efforts to ensure that high quality health care and benefits services are provided to our Nation's veterans. CAP reviews combine the knowledge and skills of the OIG's Offices of Healthcare Inspections, Audit, and Investigations to provide collaborative assessments of VA medical facilities and regional offices on a cyclical basis. The purpose of CAP reviews are to:

- Evaluate how well VA facilities are accomplishing their missions of providing veterans convenient access to high quality medical and benefits services.
- Determine if management controls ensure compliance with regulations and agency policies, assist management in achieving program goals, and minimize vulnerability to fraud, waste, and abuse.
- Conduct fraud and integrity awareness briefings for facility staff.

In addition to this typical coverage, CAP reviews may examine issues or allegations referred by VA employees, patients, members of Congress, or others.

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Combined Assessment Program Review VA Medical Center Minneapolis, Minnesota

Executive Summary

Introduction. The Office of Inspector General (OIG) conducted a Combined Assessment Program (CAP) review of VA Medical Center (VAMC) Minneapolis, Minnesota during the week of September 17 – 22, 2000. The purpose of the review was to evaluate selected medical center operations, focusing on patient care and quality management (QM), financial and administrative management controls, and fraud prevention.

Patient Care and QM. Management supported QM and performance improvement. The VAMC had a comprehensive and well organized QM program that effectively coordinated patient care activities and properly monitored the quality of care. However, some issues that related to patient care oversight and environmental conditions needed management attention.

We suggested that the Acting Medical Center Director:

- ensure documentation of chronic pain management,
- improve nutritional management in long-term care,
- improve documentation of pain assessments,
- address environment of care issues, and
- ensure confidentiality of patient information.

We also recommended that the Acting Medical Center Director and the Director, Veterans Integrated Service Network (VISN) 13 (Network Director):

- comply with agency criteria on visits to veterans in contract nursing homes (CNHs), and
- document informed consent for human research subjects.

Financial and Administrative Management. The medical center's financial and administrative activities were generally operating satisfactorily, and management controls were generally effective. To improve operations, we suggested that the Acting Medical Center Director:

- strengthen internal controls over the Government purchase card program,
- perform equipment inventories, and
- improve oversight of employee travel accounts.

We recommended that the Acting Medical Center Director:

- improve accountability for controlled substances,
- ensure that informed consents for surgical procedures are documented,
- expedite the establishment of an inventory of hazardous materials,
- enhance automated information security,
- improve Medical Care Collection Fund (MCCF) efforts,
- ensure that undelivered orders and accrued services payable are reviewed and deobligated as appropriate,
- ensure the appropriateness of on-the-spot incentive cash awards,
- improve internal controls over supply inventories, and
- improve collections of accounts receivable.

Fraud Prevention. Medical center management fully supported fraud prevention efforts. During our review, we provided four fraud and integrity awareness briefings to medical center employees.

Comments. The Acting Medical Center Director and the Network Director concurred with the recommendations and agreed with the suggestions directed to them, with the exception of one issue. Both officials non-concurred with the recommendations to adhere to VHA policy on the frequency of visits to veterans in CNHs by VAMC staff in general and by registered nurses in particular. Each asserted that the VISN 13 policy that provides for longer intervals between visits was more appropriate than the VHA policy. We will refer this issue to the Assistant Deputy Under Secretary for Health for resolution.

With the exception of the issue concerning the frequency of CNH visits, we consider all other issues in this report resolved, although we may follow up on implementation actions.

(original signed by:)
RICHARD J. GRIFFIN
Inspector General

Introduction

Organization. VAMC Minneapolis provides primary medical, mental health, and extended care; and operates three satellite clinics and two community-based outpatient clinics. The VAMC is one of five medical centers in VISN 13. The primary veteran service area for VAMC Minneapolis is the State of Minnesota and 16 counties in western Wisconsin.

Affiliations and Programs. The medical center is affiliated with the University of Minnesota for medical residencies as well as other allied health science programs such as Nutrition and Food, Nursing, Occupational Therapy, Physical Therapy, Social Work, Pathology and Laboratory Medicine, Psychology, Physician Assistants, and Dental. In FY 2000, the medical center had 150 research projects.

Resources. The FY 2000 budget was \$264 million, and staffing totaled 2,151 full-time equivalent employees, including 160 physicians. As of the 3rd quarter FY 2000, the medical center had 114 medical, 45 psychiatric, and 104 extended care beds.

Workload. In FY 1999, the medical center provided 36,444 inpatient days of care to 5,936 medical and psychiatric patients, and 33,510 inpatient days of extended care to 1,148 patients. The average daily inpatient census was 75 medical, 25 psychiatric, and 92 extended care patients. The outpatient care workload was 431,738 visits.

Objectives and Scope of Combined Assessment Program

The objectives of the CAP review were to evaluate selected clinical, and financial and administrative operations; and to provide fraud and integrity awareness training to medical center employees.

QM and Patient Care. We reviewed selected clinical activities with the purpose of evaluating the effectiveness and appropriateness of QM and patient care. The QM program is comprised of a set of integrated processes that are designed to monitor and improve the quality and safety of patient care and to identify, evaluate, and correct actual or potentially harmful circumstances that may adversely affect patient care. QM includes risk management, resource utilization management, total quality improvement, and coordination of external review activities. Patient care management is the process of planning and delivering patient care and includes patient-provider interactions, coordination among care providers, and staff competence.

To evaluate the QM program and patient care management, we inspected patient care areas, reviewed pertinent QM and clinical records, and interviewed managers, employees, and patients. We used questionnaires and interviews to evaluate employee

and patient satisfaction and solicited their opinions and perceptions about the quality of care. We reviewed the following programs and patient care areas:

Prescribing Controlled Substances
to Psychiatry Patients
Nutritional Care Management in Long-
Term Care

Contract Nursing Home Care
Pain Management
Medication Security

Financial and Administrative Management. We reviewed selected financial and administrative activities with the objective of evaluating the effectiveness of management controls. These controls are the policies, procedures, and information systems used to safeguard assets, prevent and detect errors and fraud, and ensure that organizational goals and objectives are met. In performing this review, we inspected work areas, interviewed managers and employees, and reviewed pertinent financial and administrative, and clinical records. The review covered the following financial and administrative activities and controls:

Accounts Receivable
Agent Cashier
Automated Information Systems Security
Construction Change Orders
Controlled Substances Accountability
Credentialing and Privileging
Employee Travel
Enhanced Use Leases
Equipment Accountability
Equipment Purchases
General Post Fund Accounts
Government Purchase Cards

Hazardous Materials Inventory
Informed Consents for Research
Informed Consents for Surgery
Inventory Management
Medical Care Collection Fund
Nursing Home Contracts
Procurement of Printing Services
Scarce Medical Specialist Contracts
Supply Processing and Distribution
Timekeeping for Part-Time Physicians
Undelivered Orders and Accrued Services
Payable

Fraud Prevention. We conducted 4 fraud and integrity awareness briefings for more than 100 medical center employees. The briefings included case-specific examples illustrating procurement fraud, false claims, conflicts of interest, and bribery. The briefings included handouts of a Fraud Awareness Packet and a flyer on how to report fraud, waste, or abuse in the VA Workers' Compensation Program.

Scope of Review. The CAP review generally covered medical center operations for FYs 1999 and 2000. The review was performed in accordance with "Standard Operating Procedures for Combined Assessment Program Reviews," issued by the VA OIG.

Results, Suggestions, and Recommendations

Patient Care and Quality Management

Patient Care and QM Were Generally Effective

We concluded that the VAMC Minneapolis patient care and QM programs were well managed. Clinical activities were operating effectively, as illustrated by the following examples.

The QM program was effective. We reviewed root cause analyses, administrative boards of investigation, patient incident reports, and the tort claim process. QM staff had implemented effective processes that identified opportunities for improvement, ensured appropriate follow-up on recommended corrective actions, and performed analyses of outcome data. QM staff were proactive, thoroughly investigated “near misses” (events that could have resulted in adverse patient care consequences, but did not), and worked closely with other medical center employees to identify potential errors and vulnerabilities. Documentation supported the presence of an effective organizational structure to ensure communication of QM activities throughout the facility.

Most patients and employees were satisfied with the quality of care. We interviewed medical center management, clinical managers, and 107 patients. We also sent survey questionnaires to 330 randomly selected full-time employees, 147 of whom responded (45 percent). The results of our interviews and surveys showed that 90 percent of the employees, 89 percent of outpatients, and 88 percent of inpatients rated the quality of care as good, very good, or excellent. Eighty-three percent of outpatients and 97 percent of inpatients stated they would recommend care at the medical center to family members or friends, and 76 percent of the employees interviewed indicated they would make the same recommendation.

Management demonstrated a commitment to patients and employees. The Acting Director, Chief of Staff, and Nurse Executive formed a cohesive leadership team and provided oversight for the medical center’s operations while actively supporting patient care programs. Management was determined to improve communication with employees, patients, and the public; and, hosted frequent town hall meetings and conducted rounds in patient care areas. In support of quality improvement initiatives, management established interdisciplinary work groups charged with the responsibility of ensuring compliance with JCAHO standards. The facility had recently reorganized into patient care lines to improve delivery of patient care.

Suggestions for Management Attention

We noted several clinical and QM issues that warranted management attention. We made suggestions for improvements in the following areas.

Clinicians needed to improve documentation of chronic pain management. Because of the potential for abuse, documentation of the need for long-term administration of controlled substances for pain management should be included in patient treatment plans. Medical center policy also required that treatment plans be kept current through annual reviews. However, justifications for long-term administration of controlled substances were not always part of these plans.

We reviewed 10 medical records of patients for whom controlled substances were prescribed for chronic pain management in the last year. Six records lacked current treatment plans and three had no treatment plans at all. Clinical managers should ensure that treatment plans are current and documented in the medical records for all patients being treated for chronic pain.

The Acting Medical Center Director agreed with this suggestion, noting that the VAMC had hired a Pain Coordinator just after our visit who was charged with making the needed improvements.

Documentation of pain assessments needed to be improved. We interviewed 17 clinicians directly involved in the assessment and management of pain. Fifteen of them stated they were familiar with VHA and JCAHO policy. However, only 10 said they were aware of requirements regarding documentation of pain assessments. A review of medical records showed poor documentation of data relating to pain assessments. Management should ensure that staff responsible for assessing pain in patients appropriately document those assessments.

The Acting Medical Center Director agreed to implement our suggestion.

Nutritional care management in long-term care needed improvement. We reviewed 19 long-term care patient medical records to determine if nutritional intervention was provided to patients when medically indicated. The records belonged to patients whose serum albumin levels indicated nutritional deficiencies. Documentation of patient education on dietary requirements was found in only 8 of 19 records, and documentation of interdisciplinary team reviews was present in only 3 records. In addition, facility policy did not specify when patients with nutritional deficiencies should be weighed, and we noted that patient weights were recorded inconsistently in medical records. Improvements were also warranted in documenting patient food intake, obtaining follow-up serum albumin or pre-albumin levels for nutritional assessments, and ascertaining patient food preferences. Lastly, only half of the employees interviewed believed adequate assistance was available for patients at mealtime.

The Acting Medical Center Director agreed to address deficiencies in nutritional management identified during our review.

Management needed to improve the environment of care. During tours of the facility and observation of conditions in patient care and administrative areas, we identified the following environment of care issues that required management attention:

- Improved controls for securing clean and sterile supplies in the Magnetic Resonance Imaging (MRI) section were needed.
- Cleaning solutions, chemicals, and other liquids in the MRI section were not secured.
- Patient Representative's photographs and contact information needed to be posted in all patient care areas.

The Acting Medical Center Director agreed to take action to address all of these issues, including the use of alternative methods to ensure that patients with problems or complaints had adequate access not only to the officially designated Patient Representative, but also to members of the VAMC management team.

Confidentiality of patient information was not maintained. We observed lapses in the security of sensitive patient medical data.

- Improved measures were needed to provide for confidentiality of patient records in several clinical areas and clinician offices when employees were not present.
- Patient sign-in lists in Ambulatory Care clinics needed to be posted away from public view.
- Computer screens displaying sensitive information in the Intensive Care Unit were within public view.

The Acting Medical Center Director agreed to implement measures to ensure that patient privacy is adequately safeguarded at all times.

Recommendation to Improve the Quality of Care

Medical Center and VISN CNH policies and practices did not comply with VHA and JCAHO requirements. VAMC Minneapolis staff utilized VISN 13 policy as their guideline for CNH care. However, VISN 13 policy did not comply with requirements for monthly visits to veterans, medical staff approval for new contracts and contract renewals, and requirements for the collection and analysis of performance improvement (PI) data.

VHA policy requires that:

- Medical center staff visit CNH patients every 30 days.
- Nursing staff visit patients every 60 days.
- Patients receive annual physical exams.
- The need for continuing care in the CNH is documented in the medical records.
- All renewals of existing contracts and implementation of new contracts are approved by facility medical staff.
- CNH PI data is utilized to monitor patient care.

In contrast, at the time of our visit VISN 13 policy required that visits to CNH patients be provided on an alternating basis by a social worker or a nurse only every 90 days, or more frequently, based on individual patient needs. While this was VISN 13 policy at the time of our review, that policy was revised in January 2001 and now differs even more from VHA policy. The revised policy now calls only for follow-up contacts on CNH patients every 30 days by phone from a nurse or a social worker, and visits by a registered nurse only every 180 days. In addition, there was no provision for medical staff approval of contract renewals and new contracts, and CNH PI data was not required to be used in evaluating care.

We reviewed the medical records of 10 CNH patients for documentation of monthly visits and required annual physical examinations and for clinical indications that continued CNH care was needed. Only 2 of the 10 medical records contained documentation of visits from VA staff, and no visits by VA nurses were documented in any of the 10 records. In addition, annual physical examinations were not documented in the medical records of patients who resided in CNHs for more than 1-year. Finally, there was no documentation in the 10 medical records of the need for continued CNH care.

We visited a local CNH and interviewed the facility's administrator, who stated that VA medical center staff had not visited one veteran on an indefinite contract since 1983. In addition, the CNH administrator was unaware of the need for veterans to receive annual physical examinations.

There was also inadequate medical staff review of CNH contracts. JCAHO criteria require that facility medical staff review and approve all contracts for medical care with outside medical sources. However, medical staff at the VAMC had not reviewed CNH contracts since February 1996.

Finally, there was no provision in VISN 13 policy for the collection and analysis of PI data. VHA policy requires that QM staff at each VAMC use PI indicators to improve care and make decisions about contract renewals. The medical center QM program did not provide for collection or analysis of PI data from the CNH program to assess quality of care.

These issues indicate a need for significant improvement in the CNH program. Facility and VISN 13 management should implement policies that comply with VHA and JCAHO criteria. In addition, management should put mechanisms in place to ensure that the QM and patient care activities detailed above are carried out.

Recommendation 1. The Acting Medical Center Director and the Network Director, VISN 13 should comply with VHA and JCAHO criteria to ensure that:

- a. Monthly visits by medical center staff to CNH patients are made and documented in medical records.
- b. Each veteran in a CNH is visited by a nurse every 60 days.
- c. Annual physical examinations are performed for each veteran who has been in a CNH for more than 1-year.
- d. The need for continuing care in a CNH is documented in the medical record.
- e. Medical staff approve all new and proposed renewals of existing CNH contracts.
- f. PI data is collected and analyzed to monitor patient care.

Acting Medical Center Director Comments

The Acting Medical Center Director did not concur with recommendations 1.a. and 1.b. He stated that they follow their VISN's policy of contacting the CNH monthly by telephone and reviewing records sent from the CNH. In addition, he stated that VISN policy calls for a visit by a nurse to a CNH patient only every 6 months.

The Acting Medical Center Director did concur with recommendations 1.c., 1.d., 1.e., and 1.f., and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Network Director, VISN 13 Comments

The Network Director also did not concur with recommendations 1.a. and 1.b., citing the same reasons as did the Acting Medical Center Director, and asserting that the OIG had found their VISN CNH policy acceptable at the Fargo VA Medical Center and Regional Office CAP. He concurred in the remaining parts of recommendation 1. (c. through f.). (The full text of the Network Director's comments is contained in Appendix III.)

Office of Inspector General Comments

Based on the Acting Medical Center Director's and the Network Director's comments to parts 1.c. through 1.f. of the recommendation, we consider these issues resolved but may follow up on implementation actions. We should note that no focused review of CNH oversight procedures was performed during the Fargo CAP.

As to both sets of comments to parts 1.a. and 1.b. of the recommendation regarding the frequency of visits to veterans in CNHs by VAMC staff in general and registered nurses in particular, we will refer both issues to the Assistant Deputy Under Secretary for Health for resolution.

Financial and Administrative Management

Management Controls Were Generally Effective

Medical center management had established a positive internal control environment. Financial and administrative activities reviewed were generally operating satisfactorily, and management controls were generally effective, as illustrated by the following examples.

Internal controls over construction change orders were effective. We reviewed 4 construction projects with a combined cost of \$1 million. These four projects had a total of nine change orders, all of which were executed in accordance with VHA criteria.

Healthcare professionals were licensed, credentialed, and privileged. We reviewed credentialing and privileging records for 10 medical center staff physicians. These records showed that all 10 physicians had full, active, and unrestricted licenses and that they were appropriately privileged in their areas of specialty.

General post fund (GPF) accounts were adequately controlled. As of September 2000, the VAMC had 92 GPF accounts totaling approximately \$1.7 million. VHA policy requires that funds in these accounts be used for the direct benefit of patients, and the existence of the accounts themselves must be justified by expenditure activity in the preceding 12 months. We reviewed two research and two non-research GPF accounts and found that expenditures were appropriate and that all four accounts had shown the necessary expenditure activity.

Printing practices were monitored appropriately. Federal law requires that all printing be procured by or through the Government Printing Office with the exception of non-recurring printing jobs costing under \$1,000. We found that all printing performed conformed with the law and those responsible for monitoring the cost effectiveness of printing practices were well informed on Federal requirements.

A high-cost equipment purchase was justified. We reviewed equipment purchases over \$100,000. Only one such purchase had been made within the last year, for neuro-interventional angiography equipment costing \$2 million. The purchase was justified.

Scarce medical specialist contracts were justified. We reviewed one staff-based and six procedure-based scarce medical specialist contracts and found that all were justified. Contracting staff performed cost-benefit analyses for contracts over \$500,000 as required by VHA policy, and performed price analyses for contracts below that threshold. Where Medicare rates were not available, contracting staff solicited offers from three bidders as required by Federal Acquisition Regulations.

Procedures in Supply Processing and Distribution (SPD) conformed to VHA guidelines. VHA requires SPD staff to maintain a clean and sterile environment for

medical supplies. There was no evidence that prohibited items, such as foodstuffs, were stored in SPD areas or that inappropriate items were used to sterilize or package supplies. The temperatures in all refrigerators were within specified tolerances, and all areas observed were clean and uncluttered.

Suggestions for Management Attention

During our review, we noted several financial and administrative issues that warranted management attention. We made suggestions for improvements in the following areas.

Internal controls over the Government purchase card program needed to be strengthened. VHA criteria for the Government purchase card program requires that a designated official approve all transactions within 14 days of the purchases. In addition, medical center managers are required to perform joint monthly audits of cardholder accounts, utilizing the VA Financial Service Center's random monthly quality review of purchase card activity.

Of 7,038 transactions that occurred from June 1 to August 31, 2000, 277 transactions (4 percent) had not been approved within the required 14 days. Of these 277 delinquent approvals, 167 (60 percent) were the responsibility of a particular approving official. We also found that Fiscal Service staff and the Government purchase card program coordinator were not performing joint monthly audits of purchase cards activity as required.

Management needs to ensure that all Government purchase card transactions are approved timely. The employee who was not complying with VHA criteria should be provided assistance in improving performance. If improvement does not occur, approval authority should be transferred to another employee. Finally, joint monthly audits of purchase cards activity should be performed by Fiscal Service staff and the program coordinator.

The Acting Medical Center Director agreed to implement all of our suggestions regarding the Government purchase card.

Equipment inventories were not performed timely. VHA policy requires that every Consolidated Memorandum of Receipt (CMR) be inventoried annually. We evaluated inventory records for 159 CMRs. At the time of our review, 81 CMRs (51 percent) had not been inventoried within the preceding 12 months and inventories were from 3 to 15 months delinquent. We attempted to locate 10 items of equipment from 2 CMRs. All 10 items were ultimately located, but required more than 24 hours and the concerted effort of medical center and OIG staff to locate 1 item of computer equipment valued at \$6,100. Medical center management should ensure that all CMRs are inventoried as required to ensure that all equipment is accounted for.

The Acting Medical Center Director agreed to implement our suggestion.

Follow-up of employee travel accounts should be improved. Federal law and VA policy establish procedures for authorizing, processing, and liquidating employee travel advances. To determine if these criteria were being followed, we reviewed 10 travel advances totaling \$3,781 that were outstanding as of September 2000.

At the time of our review, 7 of the 10 advances had not been liquidated. These 7 advances ranged from 1 to 10 months outstanding and totaled \$1,971. They had not been liquidated because:

- On three occasions employees failed to file travel vouchers subsequent to completion of their travel.
- On one occasion scheduled travel was canceled, but the employee failed to repay the advance.
- On one occasion a travel advance was issued that proved to be more than the cost of the travel, leaving a balance payable that the employee had not remitted.
- On one occasion Fiscal Service staff did not enter an advance into the VAMC's automated system, with the result that the advance was not identified for follow-up.
- One advance was shown pending for temporary duty travel, but the employee and administrative responsibility for follow-up had been transferred to another VAMC.

The Acting Medical Center Director agreed that travel advances would be liquidated promptly.

Recommendations for Improving Management Controls

Controlled substances were not adequately accounted for. We found serious deficiencies in accounting for controlled substances. VHA policy details procedures governing the receipt, prescription, dispensing, storage, and destruction of controlled substances. In addition, VHA policy outlines requirements for an effective controlled substances inspection program.

We requested and observed an unannounced inspection of all areas where controlled substances were stored or dispensed. We toured storage areas, interviewed staff, and reviewed reports of monthly narcotics inspections for the 12-month period September 1999 to August 2000. We identified deficiencies in the following areas:

Monthly Narcotics Inspections

The Outpatient Pharmacy and the Methadone Clinic had not been inspected for approximately 3 years. In the Outpatient Pharmacy, the inventory of controlled substances included 88 items at the time of our review. Pharmacy Service staff told us that inspections were not performed in the Outpatient Pharmacy because mainly lower

scheduled substances, Schedules III and IV, were stored and dispensed there. Staff also informed us that they were unaware that the Methadone Clinic needed to be included in monthly inspections. VHA criteria require that all controlled substances (Schedules I to IV) be inspected monthly. Failure to do so for such an extended period of time is a serious deficiency, calling into question the reliability of current balances shown in medical center accountability documents. Management should establish accurate baseline balances for these two areas and ensure that they are inspected monthly.

In addition, during the inspection conducted by VAMC staff during the period June 29 – 30, 2000, 25 of 34 ward and treatment areas were not inspected, and 12 areas were shown on June inspection documents as “incomplete.” Again, the accuracy of narcotics balances maintained in the affected locations was questionable.

Management needed to assign and train narcotics inspectors whose routine medical center duties did not involve controlled substances accountability. VA police officers performed 11 of the 12 monthly inspections we reviewed. The police officers believed, and we agreed, that this created a potential problem with separation of duties. If controlled substances are reported stolen or missing, the same police personnel who had previously attested to the accuracy of narcotics inventories could be expected to investigate the results of their own inspections.

Narcotics inspectors received no formal training on performing monthly inspections. VHA policy requires that a program of orientation and training for inspectors be established and documented. The training that was provided was informal on-the-job training and was not documented.

Physical Security, Accountability, and Destruction

Physical security and accountability of narcotics on wards and in other dispensing areas was lax. Controlled substances were left on counter tops and on top of refrigerators in ward and treatment areas. Doors to secure areas were not double-locked as required. Narcotics cabinets were left unlocked, and in one location as many as five employees had keys to a narcotics cabinet. In another location, control over the narcotics cabinet had been lost, as a secretary had several keys to the narcotics cabinet that she distributed to staff as needed.

A seal to an ampule of injectable morphine was broken with no explanation or follow-up action by the either medical or narcotics inspection staff. Notations on labels on bottles documenting contents were missing or illegible. In addition, on three occasions nine tablets were shown in accountability records to have been crushed and “in need of replacement,” but with no further actions taken by inspectors or medical staff.

Our unannounced inspection revealed a systemic problem in the way an opium tincture was measured, issued to wards, and dispensed to patients. On three different wards, the amounts of this solution were less than those indicated in accountability records.

Ward staff told us that Pharmacy Service staff did not mark the beginning balances on these bottles before they sent them to the wards. Ward staff also told us that because the solution and the bottles in which it was stored were both dark brown, accurate measurements were difficult. In addition, on one of these three wards opium tincture was not needed and should have been returned to the pharmacy.

Although maintaining accountability for liquid narcotics may be more difficult than for other forms, the consistent discrepancies found for this specific narcotic demonstrate a need for corrective actions. These actions should include improved measuring and dispensing techniques and ensuring that opium tincture or other narcotics are kept in inventory only at locations where they are needed.

Procedures for the destruction of unusable narcotics were not adhered to. On one ward, from July 31 through September 20, 2000, staff destroyed controlled substances on 18 occasions. On only one of these occasions was the destruction witnessed by a second medical center employee as required by VHA criteria. On another ward, we observed a nurse fill a syringe from an ampule, measure the amount drawn into the syringe according to the dosage required by the patient, and then empty the excess into a waste can without a witness present. Nursing staff conceded that the established procedures were not followed. We noted that monthly narcotics inspections had not identified any problems with the destruction of narcotics.

Security and Accountability of Prescription Forms

The Drug Enforcement Administration requires that prescription forms be accounted for and maintained in a secure environment. At this facility, pads of 100 each of VA Form 10-2577F, "Security Prescription Form," were serially numbered and issued to wards and other patient care areas. However, many of these forms could not be accounted for. During our narcotics inspection, we also noted unattended and unsecured prescription pads in patient care areas.

According to patient care and Pharmacy Service staff, pads of prescription forms were generally issued to "areas" rather than to individual staff members. Pharmacy Service staff told us that any ward staff, including volunteers, could obtain them. We inventoried forms shown in Pharmacy Service records as recently issued to patient care wards and found that 7 pads, or 700 forms, were unaccounted for on 2 wards.

In addition, we observed two partial prescription form pads unsecured on another ward, entire pads and individual forms being used out of sequence, and serially numbered forms and pads that were different from those shown on Pharmacy Service records. Two wards also maintained excessive supplies of prescription forms. All of these conditions significantly increased vulnerability to loss and misuse.

Documentation of Accountability for Prescription Forms

Adding to the lax controls for issuing and storing prescription forms on wards was the unreliability of documentation used to establish accountability for prescription forms. Facility staff on several occasions gave us rosters to document the location of specific forms that should have been found on wards. We were given rosters that obviously had been partially copied from other rosters and rosters that had numbers deleted at some point after they had been originally prepared. One roster had been partially copied with sequenced and typed numbers eradicated and handwritten substitutions made.

It appears that once we had begun to identify problems with accountability, the rosters used to account for prescription pads were deliberately tampered with in an attempt to quickly reconcile inventory records with actual prescription forms on hand. We shared examples of these questionable rosters with facility management.

Recommendation 2. The Acting Medical Center Director should:

- a. Address each deficiency in monthly narcotics inspections detailed above.
- b. Establish internal controls to ensure that controlled substances are stored, dispensed, and destroyed in a manner consistent with full accountability.
- c. Ensure that adequate security and accountability for drug prescription forms is maintained.
- d. Ensure that Pharmacy Service staff adequately protect rosters used to control prescription pads to avoid tampering.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with all parts of the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider these issues resolved but may follow up on implementation actions.

Controls for obtaining and documenting patient informed consents for human research needed improvement. Medical center staff responsible for monitoring research programs did not ensure that adequately documented informed consents were obtained from participating patients. As a result, staff could not provide assurance that patient rights were adequately safeguarded.

VA policy is specific about protecting the rights of human subjects involved in VA research projects. Among other provisions, VA staff are required to ensure that

informed consents are obtained from all research subjects or, in the case of those adjudged incompetent, from legally authorized representatives.

Research Service administrative staff informed us that a significant number of VA patients were participating in some or all of the approved projects conducted at the medical center. Although they were generally aware of which research projects called for the participation of human subjects, they could not provide us with a list of all patients who were participating in such research projects. In addition, they did not perform systematic reviews to ensure that informed consents were obtained from patients prior to their being enrolled in these projects. Rather, they depended on individual research investigators to obtain and document informed consents for their respective projects. Research Service administrative staff performed no reviews or oversight to ensure adherence to VA policy on patient rights.

In addition, informed consents were not maintained in patient medical records. VA policy requires that the original research consent form be maintained in each patient's medical record. However, Research Service staff informed us that it had been local practice to include only copies of the consent forms in patient medical records. This local practice had been revised just before our arrival, and an effort was underway on a "spot check" basis to place original consent forms in medical records.

To determine if individual investigators were obtaining and documenting informed consents from patients involved in their research projects, we reviewed the medical records of 10 patients whom Research Service administrative staff were able to identify as research participants. In 9 of the 10 cases, facility staff had not complied with VA policy:

- In five cases, only copies of the consent forms were in the medical records.
- In four cases, there were no consent forms in the medical records.

Based on the results of our review, we recommended that facility staff immediately review one particular research project because the protocol for that project called for inclusion of legally incompetent veterans. Given the lack of controls to protect patient rights in research at the VAMC, it is imperative to ensure that these patients are adequately protected, because they are unable to make decisions in their own best interests. In addition, Research Service staff should identify and maintain an up-to-date list of all cases of VA patient participation in research projects to enable reviews for informed consents and for other quality assurance and patient rights considerations.

Recommendation 3. The Acting Medical Center Director and the Network Director, VISN 13 should ensure:

- a. Establishment of a process that will identify all VA patients involved in human subject research projects.

- b. Establishment of an ongoing systematic review of informed consent compliance for such patients.
- c. Immediate review of informed consents for the research project that involved participation of legally incompetent patients.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with all parts of the recommendation and provided acceptable implementation plans. However, the Acting Director did not agree that the medical center's former policy represented inadequate protection of human subjects. In fact, he emphasized twice in his comments that medical center management resists any implication that human subjects have not been adequately protected at this site. (The full text of the Acting Director's comments is contained in Appendix II.)

Network Director, VISN 13 Comments

The Network Director also concurred in the recommendations, but stated that he strongly disagreed with the perceived implication that human subjects are not protected at the VAMC. In addition, he stated that a process was in place to identify patients by research project, that the medical center's review mechanism for such patients could be more expansive, and that incompetent patients were being especially protected. (The full text of the Network Director's comments is contained in Appendix III.)

Office of Inspector General Comments

We should point out that we neither stated, nor implied that human subjects involved in research projects at the VAMC were in danger. We found no such evidence. However, what we did find was that, because of a lack of appropriate documentation, VAMC staff could not provide us with the required assurance that patient rights were adequately safeguarded. We consider these issues resolved but may follow up on implementation actions.

Patient informed consents for surgical procedures were not adequately documented. VHA policy requires that informed consents be obtained and documented before any surgical or invasive procedures are performed on patients. The practitioner is required to discuss with the patient the risks of, and alternatives to, a given surgical procedure, as well as to provide and document a complete description of the surgical procedure to be performed. The practitioner and the patient (or a legally authorized representative) must sign each form, and those signatures must be witnessed. All signatures must be dated.

To determine whether informed consents were being obtained and documented, we reviewed the medical records of 14 patients who underwent surgical procedures during the month of April 2000. The physicians, patients, and their witnesses signed all 14

consent forms. However, of the 14 consent forms, 11 had 1 or more deficiencies (a total of 31). Examples of some of those deficiencies are:

- On two occasions discussions of the surgical procedures to be performed were inadequately documented.
- On one occasion there was no documentation as to whether the patient understood the implications of the information presented by the physician.
- Three forms were not dated.

To ensure that patient rights are protected, VA policy regarding patient consents must be adhered to. Management should ensure that deficiencies identified are corrected and that future compliance is monitored.

Recommendation 4. The Acting Medical Center Director should ensure that all required elements of informed consents for surgical procedures are documented in patient medical records.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider this issue resolved but may follow up on implementation actions.

Management needed to expedite a hazardous materials inventory. VHA policy requires that VAMCs develop and maintain an inventory of all hazardous chemicals that includes purchase, storage, use, and disposal information. We interviewed various staff in different parts of the medical center who were involved in the control and handling of hazardous materials. Although everyone we interviewed was aware of this policy, a complete and accurate hazardous materials inventory had not been established.

These same staff informed us that they were in the process of establishing an inventory but that the inventory being compiled could include up to 15,000 items. Based on our experience, the large number of items proposed for the inventory leads us to believe that significant numbers of non-hazardous items were also being inventoried. Medical center management should determine if all of those items are, in fact, covered by VHA policy, and delete those items from the inventory that do not require control. The inventory being developed was also unnecessarily detailed, listing manufacturers and specifications for items. Requiring such excess detail, as well as the fact that only one part-time intern was assigned to perform the inventory, slowed down the process. For these reasons, we estimate that it will take up to a year to complete the inventory.

The Acting Medical Center Director should assign adequate appropriate staff to quickly complete this inventory. These staff should develop an inventory that lists only those hazardous materials that need to be controlled and that contains only the following information for each item:

- Starting inventory levels.
- Locations.
- Staff responsible for a given material.

These steps will expedite the development of at least a preliminary inventory.

Recommendation 5. The Acting Medical Center Director should take steps to expedite the establishment of a hazardous materials inventory.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider this issue resolved but may follow up on implementation actions.

Automated information security needed improvement. The Office of Management and Budget and VHA have issued criteria to ensure that automated information is protected and that access to it is restricted and monitored. In addition, VHA requires that employees holding information technology (IT) positions undergo background investigations to clear them for access to sensitive data.

We tested facility compliance with the above criteria and found that improvements were needed. Prior to our review, we obtained a listing of all individuals who had access to the medical center's Veterans Information System Technology Architecture (VISTA) system, but who were not listed in VA's automated payroll system. This list identified 1,668 individuals and organizations. The individuals identified were not current VA employees and the organizations were not VA entities.

We reviewed the list with Information Resource Management (IRM) Service staff. They informed us that they had never performed a review of system access before, but noted that many of those included on our list were fee basis contractors. They stated that local policy allows each medical center service to grant VISTA access and that, apparently, access for contractors and former employees was not being terminated when their services were no longer required. In addition, the Information Security

Officer (ISO) and 12 of 14 staff from IRM Service had not undergone background checks.

The ISO function needs to be strengthened. The ISO told us that she is able to perform her IT-related tasks only part-time because she is the full-time facility librarian. VHA policy states that part-time ISOs must be assigned those duties as their primary responsibility, with other duties assigned only collaterally. In addition, the ISO stated that she had informed facility management that she needed an Assistant ISO (AISO) with a strong IT background because she did not have the expertise to address many of the IT-related problems that she had identified. At the time of our review, facility management had not provided an AISO.

Problems attributable to the lack of a strong technical background of the ISO included:

- The ISO was aware of instances of unauthorized individuals accessing patient medical records, as reported in an internal IRM security log. However, she did not pursue security incident reporting because she was not aware of the necessary procedures, and she did not know how to solve the problem of unauthorized access.
- IRM staff had informed the ISO that there were several non-IRM employees who had access authority and system privileges appropriate only for IRM staff. Again, the ISO did not address the issue because she was unsure how to proceed.
- Although the facility did implement an IT contingency plan in April 2000, the plan was incomplete. It did not include addresses of key personnel, and it did not designate a pre-arranged meeting place for key personnel in the event communications were disrupted.
- Employee Internet and Local Area Network usage was not routinely monitored.
- Facility staff had not developed an overall IT security plan.

Management should ensure that all individuals with VISTA access who are not employed by the facility and who no longer require access have their access terminated. In addition, all individuals with high-level access to facility data systems should have documented security clearances on file. Finally, other fundamental and systemic problems relating to basic IT organization, staffing, and expertise should be addressed by facility management.

Recommendation 6. The Acting Medical Center Director should:

- a. Ensure that only individuals with established needs have access to the facility VISTA data.
- b. Require security clearances be obtained and documented for individuals with high-level access to automated data systems.

- c. Appoint an AISO.
- d. Ensure that the positions of ISO and AISO are occupied by individuals who have the resources and technical expertise necessary to perform their duties.
- e. Take action to prevent unauthorized access to facility data systems.
- f. Take action to limit system access and system privileges to only staff whose duties require it.
- g. Correct deficiencies in the IT contingency plan.
- h. Develop an overall facility IT security plan.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with all parts of the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider these issues resolved but may follow up on implementation actions.

Management needed to reduce the MCCF backlog. Federal regulations and VHA policy require that VHA facilities bill third party insurers for medical care provided to non-service connected veterans who do not meet means test eligibility requirements. As of September 5, 2000, there were 262 inpatient episodes of care and 48,519 outpatient visits that should have been billed to third party carriers. The total value of the unbilled inpatient and outpatient care was approximately \$2.1 million and \$10.3 million, respectively. Thus, approximately \$12.4 million in third party cases needed to be processed for billing.

This condition occurred because of a lack of timely actions on the part of the MCCF staff. In a judgment sample of five third party cases, we found that that billing staff had not established bills timely in four of the five cases. The average processing time from the date outpatient care was provided, or an inpatient was discharged, to when a bill was generated was 80 days. In contrast, private sector healthcare organizations bill at least every 30 days. Using the medical center's average established recovery rate of 24 percent for third party billing, we estimate that approximately \$3 million of the \$12.4 million outstanding could be collected if billed timely (24 percent x \$12.4 million).

Recommendation 7. The Acting Medical Center Director should reduce the MCCF backlog and improve collections by ensuring that third party billings are processed timely.

(The monetary benefit associated with this recommendation is shown in Appendix I.)

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider this issue resolved but may follow up on implementation actions.

Undelivered orders and accrued services payable were not reviewed in accordance with VA policy. Our review of undelivered orders showed that follow-up was inadequate. As of August 31, 2000, the "Undelivered Orders Report" showed 917 orders with outstanding balances of approximately \$7.1 million. In a judgment sample of five of these orders with outstanding balances of \$169,612, we found that two orders totaling \$15,470 were no longer needed. Those funds should be deobligated and, because they were from a prior fiscal year, returned to the U.S. Treasury.

Accrued services payable accounts also needed closer attention. As of August 31, 2000, there were 1,112 accrued services payable accounts totaling approximately \$11 million. A judgment sample of five outstanding payables valued at \$311,932 revealed that three, totaling \$195,669, had not been liquidated timely. For example, a payable of \$182,352 for a rental agreement with the General Services Administration had not been deobligated even though the account had shown no activity since October 1997. Based on this longstanding inactivity, this payable should be reviewed and, if the rental agreement is unneeded, the funds obligated in a prior fiscal year should be returned to the U.S. Treasury.

Medical center management should ensure that Fiscal Service staff responsible for maintaining these accounts monitor them and deobligate funds as needed. In addition, a total of \$211,139 (\$15,470 from undelivered orders plus \$195,669 from accrued services payable) should be deobligated.

Recommendation 8. The Acting Medical Center Director should ensure that:

- a. All undelivered orders and accrued services payable are reviewed and deobligated when appropriate.
- b. Deobligate the two undelivered orders and three accrued services payable identified by our review.

(The monetary benefit associated with this recommendation is shown in Appendix I.)

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with both parts of the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider these issues resolved but may follow up on implementation actions.

The use of on-the-spot incentive cash awards was inappropriate. On-the-spot incentive cash awards were used inappropriately in Nursing and Dietetic Services. In July and August 2000, these awards totaled \$37,000. VA policy states that these awards can be given to employees for high performance or other special contributions. Their purpose is to recognize and reward individual achievements that contribute to meeting organizational goals or improving the efficiency, effectiveness, and economy of operations.

We reviewed a hotline allegation received during the CAP review concerning the use of on-the-spot incentive cash awards and found that awards were given to Nursing Service staff daily if they agreed to work additional shifts. Awards were also routinely given to Dietetic Service staff if they agreed to work overtime. The Agent Cashier operated a separate window just to process the high volume of awards.

Medical center management explained that this practice was in reaction to a severe staff shortage in Nursing Service. They also stated that staff shortages existed in Dietetic Service, although to a lesser degree. They believed that unless they offered nurses incentives for working additional shifts, they would leave VA and find other jobs at higher wages. However, VA policy is very clear that incentive awards, including on-the-spot incentive cash awards, are inappropriate when used:

- To recognize additional hours of work when overtime pay or other compensatory time was provided for those additional hours.
- As an incentive to encourage employees to work in a particular area or on a particular shift.

Although we recognize management's nursing shortage dilemma, we believe they must seek remedies other than the inappropriate use of on-the-spot awards.

Recommendation 9. The Acting Medical Center Director should stop the inappropriate use of on-the-spot incentive cash awards in Nursing and Dietetic Services.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider this issue resolved but may follow up on implementation actions.

Inventory controls over medical supplies in the warehouse and SPD needed strengthening. Improvements were needed in managing inventory in the warehouse and SPD. VHA policy stresses the need for facility management to emphasize inventory controls in their operating and business plans.

Emergency levels of stocks were not maintained. According to the "Emergency Stock Level Report" for both SPD and the warehouse, there were numerous occasions when supplies of emergency stocks fell below minimum acceptable inventory levels. Our test on September 19, 2000, showed that of 104 designated emergency items listed for SPD, inventories of 85 items (82 percent) were below appropriate stock levels. Of 43 designated emergency items listed for the warehouse, inventories of 32 items (74 percent) were below emergency levels. Each medical center designates those items that are considered emergency stock, and what the minimal levels are for each item. Therefore, the VAMC is not in compliance with its own established minimums.

In contrast to some emergency stock items falling below set minimums, a significant number of other inventory items exceeded the 30-day maximum stock level identified in VHA policy. SPD staff maintained 281 separate line items with a total value of \$718,468, of which 241 (86 percent) were in quantities that exceeded the 30-day level. The value of excess stock in SPD was \$645,787.

There was also excess stock in the warehouse. The warehouse contained 877 items with an inventory value of \$262,823 of which 597 (68 percent) exceeded the 30-day supply level. The value of excess stock in the warehouse was \$195,030.

Inventories in SPD and the warehouse could be reduced by a total of \$840,817 (\$645,787 in SPD and \$195,030 in the warehouse). Improved inventory controls would result in better use of these funds.

Recommendation 10. The Acting Medical Center Director should ensure that:

- a. Emergency levels of critical medical supply items are maintained.
- b. Excess stock levels of items are not maintained.

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with both parts of the recommendation and provided acceptable implementation plans. The Acting Director specifically stated they would work toward smaller inventory levels, although he disagreed that a 30-day supply was always appropriate for every item. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider these issues resolved but may follow up on implementation actions.

Management of accounts receivable should be improved. VA policy requires that accounts receivable be recorded in the accounting period accrued, reconciled monthly, promptly collected, and reviewed monthly for collection potential. As of September 7, 2000, there were 1,590 accounts receivable totaling approximately \$1.3 million. However, applying VA policy we concluded that 33 accounts totaling approximately \$425,000 should have been written off due to age and other factors.

Fiscal Service staff's lack of understanding of regulatory criteria and basic principles that govern the management of accounts receivable contributed to the size of the required write-off. Fiscal Service staff could not explain the significance or relevance of the tasks they were assigned to complete, nor could they explain the ramifications of noncompliance with regulatory guidance and principles. For example, although they sent three demand letters to debtors as required, they took no other follow-up action if debtors failed to respond. In addition, Fiscal Service staff told us that they were unsure of the procedures to offset employee salaries in the event of unresolved employee debts, and they were not sure that all accounts receivable were being identified. Finally, Fiscal Service staff did not conduct monthly reviews of accounts receivable for collection potential.

The loss of key staff, inadequate training, and the fact that the Accounting Section supervisor was located at another VAMC adversely impacted the ability to follow up on accounts receivable. As a result, prompt, timely, and aggressive collection actions were not always taken, opportunities were lost to recover at least some portion of the \$425,000 that needed to be written off, and collection of the \$875,000 accounts receivable balance is at risk. Facility management should review accounts receivable activities and initiate needed improvements.

Recommendation 11. The Acting Medical Center Director should ensure that:

- a. Approximately \$425,000 in uncollectible receivables are written off.
- b. Employees responsible for collecting accounts receivable are adequately trained.
- c. Appropriate actions are taken to collect accounts receivable.

(The monetary benefit associated with this recommendation is shown in Appendix I.)

Acting Medical Center Director Comments

The Acting Medical Center Director concurred with all parts of the recommendation and provided acceptable implementation plans. (The full text of the Acting Director's comments is contained in Appendix II.)

Office of Inspector General Comments

We consider these issues resolved but may follow up on implementation actions.

**Monetary Benefits in
Accordance With IG Act Amendments**

Report Title: Combined Assessment Program Review
VA Medical Center Minneapolis, Minnesota

Report Number: 00-02097-46

<u>Recommendation Number</u>	<u>Category/Explanation of Benefits</u>	<u>Better Use Of Funds</u>
7	Reduction of MCCF Backlog	\$3,000,000
8	Deobligation of Unliquidated Obligations	211,139
11	Better Follow-up of Accounts Receivable	<u>210,000¹</u>
	Total	\$3,421,139

¹ Using the VAMC's established recovery rate for MCCF billings (24 percent), we estimate that 24 percent of the \$875,000 in outstanding accounts receivable could be recovered, or \$210,000.

Acting Medical Center Director Comments

**Combined Assessment Program Review (Dated OIG Draft 7/30/01)
VA Medical Center
Minneapolis, Minnesota**

VISN 13/Minneapolis VAMC Response

Minneapolis VA Medical Center response to this report follows:

[Provided via e-mail on October 5, as modified by mutual agreement in subsequent telephone calls.]

Recommendation #1

The Acting Medical Center Director and the Director, VISN 13 should develop CNH policies that comply with VHA and JCAHO criteria to ensure that:

a. & b. Monthly visits to CNH patients are made and documented in medical records. Each veteran in a CNH is visited by a nurse every 60 days.

Action: Follow-up contacts are being completed monthly for those veterans on a contract greater than 31 days. This process is completed via phone calls and obtaining/reviewing pertinent records from the CNH. On site visits are being made at a minimum by a VA nurse every six months. (This is in accordance to VISN 13 policy V13-ECPSL-3).

Recommendations as stated are not being followed, as we are following our VISN policy which states monthly "contacts" will be made by either visits or phone calls, and nurses will visit every 6 months.).

c. Annual physical examinations are performed for each veteran who has been in a CNH for more than 1 year.

Concur

Action: We are obtaining annual physical exams for all veterans who have been in a CNH for more than one year.

d. The need for continuing care in a CNH is documented in the medical record.

Concur

Action: This will be done.

e. Medical staff approve all new and proposed renewals of existing CNH contracts.

Concur

Action: Contracting office prepares a report which is forwarded to Medical center leadership for review.

f. Ensure that PI information is collected and analyzed to monitor patient care.

Concur

Action: As part of the annual inspection, facility PI information is collected and analyzed by the review team. (This PI information also includes patient satisfaction data).

Acting Medical Center Director Comments (Continued)

Recommendation #2

The Acting Medical Center Director should:

a. Address each deficiency in monthly narcotics inspections detailed above.

Concur

Action: The change in the process of how we count tablets and the baseline inventory were both implemented in October 2000. Methadone Clinic is now part of the medical center monthly narcotic check and a baseline inventory were both done in October 2000.

b. Establish internal controls to ensure that controlled substances are stored, dispensed and destroyed in a manner consistent with full accountability.

Concur

Action: Pharmacy is dispensing the liquid narcotics with a beginning balance and the bottles are also marked with additional calibrations for inventory control, effective September 2001.

c. Ensure that adequate security and accountability for drug prescription forms is maintained.

Concur

Action: Pharmacy will issue these forms to the PSL [patient service line] departments and will have a process to track the individual serial number of the forms, effective October 2001. Pharmacy will work with the PSL leadership to monitor forms in patient care areas and develop a process for issuing and tracking prescription forms to individual providers.

d. Ensure that Pharmacy staff adequately protect rosters used to control prescriptions pads to avoid tampering.

Concur

Action: Rosters will be completed by Pharmacy Outpatient area and maintained effective October 2001.

Recommendation #3

The Acting Medical Center Director and the Director, VISN 13 should ensure:

a. Establishment of a process that will identify all VA patients involved in human subject research projects.

Concur

Action: Since November 2000 we have required investigators to provide a list of all subjects enrolled in research protocols involving humans when they apply for continuing review. This represents a change of our previous policy in which we asked individual investigators to maintain a list of research participants which would be available to the Research Office. We have therefore concurred with the IG recommendation but do not agree that the former policy represented inadequate protection of human subjects.

b. Establishment of an ongoing systematic review of informed consent compliance for such patients.

Concur

Acting Medical Center Director Comments (Continued)

Action: Since March 2001, a subcommittee of the Human Studies Subcommittee has conducted in-depth reviews of selected research protocols. Four experienced study coordinators review a different protocol each quarter. Among the criteria established for these reviews are that the consent documents are properly filed in the participant's medical records as well as in the investigator's files and with the patient. Procedures for correction of deficiencies and compliance have been established as part of this review. Another component of this review is evaluation of the procedures used by the investigators to obtain an informed consent in these studies.

Further a review conducted recently of 44 patient's charts found 100% compliance at this medical center with the standard of consent availability in the patient chart. This standard rule continues to be a review criteria on an on-going basis.

Minneapolis VA Medical Center personnel strongly dispute the implication that human subject's rights have not been adequately protected. The review conducted focused on documentation compliance, not on compliance related to performance in individual research protocols. Compliance activities related to these projects should involve education for investigators, which we have done. In addition, we have taken the following steps: prospective review of protocols and consent forms to ensure appropriate risk/benefit relationships as well as full disclosure of research plans and risks to prospective subjects; on-going assessment of events related to these research operations and the potential need to change protocols and consent forms related to evolving clinical and research data; and on-going review of active protocols for continuing judgments regarding risk/benefit and appropriateness of disclosure. We believe in each of these areas that the human studies operation at the Minneapolis VA Medical Center has performed appropriately. We resist any implication that human subjects have not been adequately protected at this site.

c. Immediate review of informed consent for the research project that involved participation by incompetent patients.

Concur

Action: It should be noted that informed consent in projects involving incompetent patients is an area of special concern for the Human Studies Subcommittee at the Minneapolis VA and this matter receives special attention each time such a protocol appears with the subcommittee. In addition protocols involving vulnerable subjects are more likely to be included in our on-going review described in the response to the above. Further special training and education discussions have taken place with every investigator who proposes to enroll incompetent subjects in a research activity.

Recommendation #4

The Acting Medical Center Director should ensure that all required elements of informed consents for surgical procedures are documented in patient medical record.

Concur

Action: The Medical Director, Specialty Care Patient Service Line, has sent a memorandum to all physicians that effective October 1, 2001, all elements of informed consent for surgical procedures will be documented in the patient's medical record.

Acting Medical Center Director Comments (Continued)

Recommendation #5

The Acting Medical Center Director should take steps to expedite the establishment of a hazardous materials inventory.

Concur

Action: We have two databases that are relevant to the IG critique, namely, one that meets OSHA requirements for employee right-to-know and a second that is comprised of hazardous substances only. The first is an extensive inventory of all products and chemicals in our facility that require a material safety data sheet (MSDS) and is managed by Safety Office personnel. All of our VA employees are knowledgeable of our MSDS Program and would address most reviewers' questions from that framework.

The second database is an inventory of our most hazardous substances only and tracks the following: (a) user, (b) product/chemical, (c) location, (d) quantity on hand, (e) date received and (f) disposal date. Included in this inventory are the carcinogens, mutagens, heavy metals, explosives, biological toxins, and substances that are highly chemically reactive, corrosive, and/or flammable. Currently, this inventory contains 655 entries, however, many substances are listed more than once. For example, formalin/formaldehyde is listed 39 times because of multiple users and user sites. Moreover, each of these substances is bar-coded for tracking purposes. This inventory is managed by our Chemical Hygiene Officer (CHO), who is also responsible for the disposal of hazardous substances from our facility.

Recommendation #6

The Acting Medical Center Director should:

a. Ensure that only individuals with established needs have access to facility Vista data.

Concur

Action: The VA Upper Midwest Health Care Network (VISN 13) is managing a VISN-wide security program, which includes implementing the mandates identified in the VA Information Security Management Plan and implementing operational security changes at all VISN 13 VAMC sites, including the Minneapolis VAMC.

The VISN plan is underway and in varying states of compliance at each site. Minneapolis is currently in the phase of completing new user access forms and security agreement forms. Departmental managers were asked to identify, for each individual in their group, essential accesses to perform current position responsibilities. Managers were advised to carefully review individual accesses and the establish essential vs. preferential accesses.

When these electronic computer access forms are completed, the VISN-wide security team will compare the information with the Vista accesses currently in place and remove non-core privileges, which may be associated with previous positions, be non-essential, and be higher-than-required for the position. The security team will also review the appropriateness of the accesses requested for each individual based on job position.

The VISN-wide security team (including HRM representatives) is also currently reviewing the need to standardize system accesses for job classifications in order to manage current and future

Acting Medical Center Director Comments (Continued)

background investigations needs for identified sensitive positions. A preliminary review of Minneapolis information reveals a need to move the concurrent responsibility for assigning user accesses, menus and keys from non-IRM staff to exclusively IRM personnel, which will ensure appropriate background investigations are ordered for individuals setting up system privileges. Minneapolis has identified October 22, 2001, as the new deadline for completing the new access forms and security agreement forms. The VISN IRM organization plans to remove non-core accesses by November 22, 2001. At the time of removal, the responsibility of assigning user accesses will become exclusively a Minneapolis IRM responsibility.

b. Require security clearances be obtained and documented for individuals with high level access to automated data systems.

Concur.

Action: The Minneapolis HRM Department is ordering background investigations that are consistent with system access needs and with VA defined position sensitivity levels. To date, Minneapolis had ordered background investigations for most staff impacted. However, HRM is currently reviewing the investigations ordered to ensure that they are consistent with those required for compliance with National security mandates for sensitivity levels. If they are not, Minneapolis HRM will initiate the appropriate changes.

The estimated deadline for HRM to complete background investigation orders is October 31, 2001.

c. Appoint an AISO.

Concur.

Action: The prerequisite to appointing an AISO, however, is hiring a full-time Minneapolis Facility ISO. Minneapolis advertised for a full-time Facility ISO with technical background and security experience. HRM is currently rating applicants to prepare for interviews. We anticipate hiring a Facility ISO by November 1, 2001.

An AISO position is warranted based on the size and operational complexity of the Minneapolis VA Medical Center. After the Facility ISO is hired, this individual will give input to the VISN-wide ISO team and assist in defining an approach for appointing a collateral duty AISO or hiring a full-time AISO. Current union agreements restrict us from appointing a full-time AISO without first posting the position internally. Based on the anticipated turnaround time on the hiring process, we identified an AISO by May 1, 2001.

d. Ensure that positions of ISO and AISO are occupied by persons who have the resources and technical expertise necessary to perform their duties.

Concur.

Action: To implement the VA security mandates regularly released, a Facility ISO requires both technical expertise and security experience.

As mentioned for Item C., the Minneapolis Facility ISO position was advertised. We are currently in the process of hiring a full-time Facility ISO. We anticipate filling this position by November 1, 2001. We expect to define and fill the AISO position by May 15, 2002.

Acting Medical Center Director Comments (Continued)

e. Take action to prevent unauthorized access to facility data systems.

Concur.

Action: The Minneapolis VAMC is currently implementing the VA security mandates issued by the Under Secretary for Health in the VA Information Security Management Plan. Accordingly, we are implementing the short-term and long-term actions identified, including mandates for IT system security, user access, security training, and background investigations. Deadlines for the security mandates are nationally determined. For specific information about Minneapolis performance in meeting these security directives, please contact MISS regarding the VISN-13 compliance reports filed.

f. Take action to limit system access and system privileges to only staff whose duties require it.

Concur.

Action: Plans and deadlines described in Items a and b.

g. Correct deficiencies in the IT contingency plan.

Concur.

Action: The Minneapolis IT systems, like all IT systems at the VISN 13 facilities, are part of a VISN-wide integrated systems architecture and are maintained by a VISN-wide IRM Group. For this reason, the VISN IRM Group is developing an IT contingency plan that will establish contingency planning and disaster recovery actions for all IT systems in the VISN. The deadline for completing the VISN 13 IT Contingency Plan is April 1, 2002.

h. Develop an overall facility IT security plan.

Concur.

Action: The VISN-wide IRM Group and VISN information security team will develop a VISN-wide IT security plan that will establish facility IT security at all sites. The deadline for completing this plan is April 1, 2002.

Recommendation #7

The Acting Medical Center Director should reduce the MCCF backlog and improve collections by ensuring that third party billings are processed timely.

Concur

Action: Two billers (2.00 FTE's) are now assigned to the inpatient billing process as of 9/15/01. Prioritizing bills with the greatest opportunity for revenue generation and additional staff assignment will reduce the inpatient billing backlog.

Changes in biller/coder processes have been established as of 09/15/01 to maximize efficiency in this process. However, manpower issues continue to be problematic. Three additional (3.00 FTE's) in billing positions and two coder (2.00 FTE's) are needed to resolve current and future backlog of outpatients handing bills. This will be accomplished by coordination of employment issues with human resources.

More awareness and education of medical staff need to be initiated, to address inordinate time spent by billers and coders reviewing clinical documentation to establish accurate and legal billing information

Acting Medical Center Director Comments (Continued)

Recommendation #8

The Acting Medical Center Director should ensure that:

a. All undelivered orders and accrued services payable are reviewed and deobligated when appropriate.

Concur

Action: The undelivered orders and accrued services payable are reviewed monthly. Orders that have had no activity for 90 days are followed up on with the ordering Department to verify whether the order is still valid. A monthly FMS extract is generated that is sorted by accounting technician and FCP to assist with the review process.

b. Deobligate the two undelivered orders and three accrued services payable identified by our review.

Concur

Action: Undelivered orders and accrued services payable identified at the time of the audit were deobligated. To verify that this was accomplished, request that the obligation numbers of the items in question be provided.

Recommendation #9

The Acting Medical Center Director should stop the inappropriate use of on-the-spot incentive cash awards in Nursing and Dietetics.

Concur

Action: On-the-spot incentive cash awards ceased at the time of the IG visit, September 2000.

Recommendation #10

The Acting Medical Center Director should ensure that:

a. Emergency levels of critical medical supply items are maintained.

Recommendation 10a. – Concur.

Action: As of January 2001, I am satisfied that we have adequate levels of designated emergency items on hand.

b. Excess stock levels of items are not maintained.

Recommendation 10b. – Concur.

Action: The VAMC is aware that it has too much stock on hand on some items and that these quantities should be reduced. We will continue to work toward more reasonable levels. However, it should be recognized that an arbitrary maximum level of 30 days on all items is not feasible. Some items have long lead times that make it difficult to coordinate deliveries from vendors with issues to customers. Others, such as specialized items for Surgery, are used rarely but must be available in inventory on very short notice (same day as requested). And finally, the VAMC has adopted a customer service approach to inventory management where we assume responsibility for managing many items that don't meet VA's definition of a recurring use item. We prefer having the logistics staff use their expertise to manage these items even if they

Acting Medical Center Director Comments (Continued)

occasionally exceed 30 day levels rather than leaving it to customers who have little expertise and may not do any management.

Recommendation #11

The Acting Medical Center Director should ensure that:

a. Approximately \$425,000 in uncollectible receivables are written off.

Concur

Action: Uncollectible receivables were written off at the time of the audit. To verify that this was accomplished, request that the receivable numbers of the items in question be provided

b. Employees responsible for collecting accounts receivable are adequately trained.

Concur

Action: Fiscal and the Business Office will work together to link the Accounts Receivable Assistants in VISN 13. This will enhance and facilitate cross communication, best practices, coordination of efforts and questions (policy, how do you do this, what do you do in this situation). The linkage will be accomplished via e-mail, conference calls and site visits.

c. Appropriate actions are taken to collect accounts receivable.

Concur

Action: Collections of account receivables are accomplished in accordance with VA collection policies.

Suggestions

We agree to implement all suggestions as discussed following the text of each suggestion in the body of this report.

Network Director, VISN 13 Comments

Department of
Veterans Affairs

MEMORANDUM

Date: October 4, 2001

From: Network Director (10N13)

Subj: Responses to draft report, OIG CAP Review of VAMC
Minneapolis – Project No. 2000-02097-R4-0274



To: William V. Deprospero, Director
OIG Chicago Audit Operations division (52CH)

1. Attached are my responses to the two recommendations (#1a and #3) where Network Director's comments were specifically requested. I agree with the Acting Medical Center Director's responses to all the other recommendations. As you can see, we concur with all others except for Recommendation 1a.
2. I appreciate the review. It was helpful and informative as have been all the IG reviews in this Network. We all appreciate the interaction with the IG reviewers.
3. Finally, thank you for the opportunity to respond to the recommendations.

ROBERT A. PETZEL, MD

Attachment

Network Director, VISN 13 Comments (Continued)

Combined Assessment Program Review of VAMC Minneapolis
(Draft Report dated 7/30/01)

VISN 13 Network Director's Response

Recommendation #1

The Acting Medical Center Director and the Director, VISN 13 should develop CNH policies that comply with VHA and JCAHO criteria to ensure that:

a. & b. Monthly visits to CHN patients are made and documented in medical records. Each veteran in a CNH is visited by a nurse every 60 days.

I agree with the VAMC Minneapolis response and do not concur in this recommendation. Extended Care and Rehabilitation PSL [patient service line] policy #3 (enclosed) states our follow up policy as requiring monthly telephone contact by a nurse or social worker and a visit once every six months by the nurse. We are aware this is not consistent with VACO guidance. However, we think that our policy provides for effective follow up of these patients, ensures that their care is coordinated and that the nursing home care is effective and safe. It is impractical and unnecessary to visit all 128 patients in this widely-dispersed network. My understanding is that Extended Care in VACO is considering revising this part of their guidance to encourage more flexibility. Finally, the IG recently reviewed this practice at the Fargo VAM&ROC and found it acceptable.

Otherwise I concur with all the other sub-recommendations (c-f).

Recommendation #3

The Acting Medical Center Director and the Director, VISN 13 should ensure:

a. Establishment of a process that will identify all VA patients involved in human subject research projects.

A process is in place that identifies all VA patients involved in human subject research and identifies them by project.

b. Establishment of an ongoing systematic review of informed consent compliance for such patients.

I agree with the medical center management that a review mechanism is in place. I also agree that it could be more expansive and that will be done. I strongly disagree with the implication that human subjects are not protected at the VAMC. This is patently not consistent with the facts.

c. Immediate review of informed consent for the research project that involved participation by incompetent patients.

Again, I agree that the incompetent patients need to be especially protected. But I disagree that this is not happening.

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