



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

Office of Healthcare Inspections

Report No. 07-02948-81

Combined Assessment Program Review of the VA Caribbean Healthcare System San Juan, Puerto Rico



February 21, 2008

Washington, DC 20420

Why We Did This Review

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

- Evaluate how well VA facilities are accomplishing their missions of providing veterans convenient access to high quality medical services.
- Provide fraud and integrity awareness training to increase employee understanding of the potential for program fraud and the requirement to refer suspected criminal activity to the OIG.

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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Executive Summary

Introduction

During the week of October 15–19, 2007, the OIG conducted a Combined Assessment Program (CAP) review of the VA Caribbean Healthcare System (the system), San Juan, PR. The purpose of the review was to evaluate selected operations, focusing on patient care administration and quality management (QM). During the review, we also provided fraud and integrity awareness training to 251 system employees. The system is part of Veterans Integrated Service Network (VISN) 8.

Results of the Review

The CAP review covered five operational activities. We made recommendations in three of the activities reviewed. For these activities, the system needed to:

- Evaluate and disclose adverse events in accordance with Veterans Health Administration (VHA) policy.
- Require the peer review process to comply with system and VHA policy.
- Complete root cause analyses (RCAs) in accordance with VHA policy.
- Require the mortality review process to comply with VHA policy.
- Require the utilization management (UM) program to comply with VHA policy.
- Require high-risk area reviews and oversight to comply with system and VHA policy.
- Store supplies and materials in accordance with National Fire Protection Association (NFPA) codes.
- Repair or replace the two fire egress doors in the Nursing Home Care Unit (NHCU).
- Complete and document preventative maintenance inspections (PMIs) on medical equipment.
- Require that housekeeping closets containing hazardous chemicals are secured when unattended.
- Ensure that high-volume public bathrooms are cleaned frequently enough to maintain a safe and hygienic environment.
- Ensure that ceiling tiles and ceiling tile grids are cleaned and replaced, as needed.

- Ensure that the Environment of Care (EOC) Committee reviews Interim Life Safety Measures (ILSM) assessments and fire safety inspection data.
- Monitor completion of mandatory customer service training.

The system complied with selected standards in the following two activities:

- Computerized Patient Record System (CPRS) Business Rules.
- Surgical Care Improvement Project (SCIP).

This report was prepared under the direction of Christa Sisterhen, Associate Director, Atlanta Office of Healthcare Inspections.

Comments

The Acting VISN and System Directors agreed with the CAP review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 19–29, for the full text of the Directors' comments.) We will follow up on the proposed actions until they are completed.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Introduction

Profile

Organization. The system is comprised of a tertiary care medical center located in San Juan, PR, and six community based outpatient clinics (CBOCs) located in Ponce, Mayaguez, Arecibo, and Guayama, PR, and in St. Thomas and St. Croix in the U.S. Virgin Islands (USVI). The system is part of VISN 8 and serves a veteran population of about 150,000 in a primary service area that includes Puerto Rico and the USVI.

Programs. The system provides medical, surgical, mental health, geriatric, rehabilitation, spinal cord injury, and dental services. It has 457 operating beds (including 149 NHCU beds and 12 blind rehabilitation beds) and also has a sharing agreement with Fort Buchanan military base.

Affiliations and Research. The system is affiliated with three medical schools in Puerto Rico which are accredited by the Liaison Committee on Medical Education: (1) the University of Puerto Rico (UPR), (2) the Ponce School of Medicine, and (3) the Universidad Central del Caribe. There are 138 VA-paid medical residents in 23 different residency training programs. The system is also affiliated with the UPR Schools of Dentistry, Pharmacy, and Nursing and with other allied health profession schools.

In fiscal year (FY) 2007, the system research program had 154 projects and a budget of approximately \$1 million. Important areas of research include hematology and oncology, infectious diseases, psychiatry, and an educational program in bioterrorism.

Resources. In FY 2007, medical care expenditures totaled approximately \$324.5 million. The FY 2008 medical care budget is approximately \$341 million. FY 2007 staffing was 3,044 full-time employee equivalents (FTE), including 392 physician and 701 nursing FTE.

Workload. In FY 2007, the system treated 64,792 unique patients and provided 72,683 inpatient days in the hospital and 29,604 inpatient days in the NHCU. The inpatient care workload totaled 7,927 discharges, and the average daily census, including nursing home patients, was 340. Outpatient workload totaled 778,439 visits.

Objectives and Scope

Objectives. CAP reviews are one element of the OIG's efforts to ensure that our Nation's veterans receive high quality VA health care services. The objectives of the CAP review are to:

- Conduct recurring evaluations of selected health care facility operations, focusing on patient care administration and QM.
- Provide fraud and integrity awareness training to increase employee understanding of the potential for program fraud and the requirement to refer suspected criminal activity to the OIG.

Scope. We reviewed selected clinical and administrative activities to evaluate the effectiveness of patient care administration and QM. Patient care administration is the process of planning and delivering patient care. QM is the process of monitoring the quality of care to identify and correct harmful and potentially harmful practices and conditions.

In performing the review, we inspected work areas; interviewed managers and employees; and reviewed clinical and administrative records. The review covered the following five activities:

- CPRS Business Rules.
- EOC.
- Patient Satisfaction.
- QM.
- SCIP.

The review covered system operations for FY 2006 and FY 2007 and was done in accordance with OIG standard procedures for CAP reviews. We also followed up on selected health care recommendations from our prior CAP review of the system (*Combined Assessment Program Review of the VA Medical Center, San Juan, Puerto Rico*, Report No. 05-00709-01, October 7, 2005). The system had attempted to correct all health care related findings from our prior CAP review; however, not all actions were effective, as described below:

- The system needed to improve colorectal cancer management. The original action plan included referral

of patients to the community for gastroenterology consultation. This action did not have the desired effect and resulted in lengthier waiting times. Managers discontinued this practice and maximized in-house gastroenterology services. Although the system still did not meet targets for colorectal cancer screening in FYs 2006 or 2007, improved scores show that actions taken have been effective. Managers continue to monitor progress in these areas.

- The system needed to improve the timeliness of RCA aggregate reviews. Further details are discussed in the QM section of this report.

During this review, we also presented fraud and integrity awareness briefings to 251 employees. These briefings covered procedures for reporting suspected criminal activity to the OIG and included case-specific examples illustrating procurement fraud, conflicts of interest, and bribery.

In this report, we make recommendations for improvement. Recommendations pertain to issues that are significant enough to be monitored by the OIG until corrective actions are implemented. Activities in the “Review Activities Without Recommendations” section have no reportable findings.

Results

Review Activities With Recommendations

Quality Management

The purposes of this review were to determine if: (a) the system had a comprehensive, effective QM program designed to monitor patient care activities and coordinate improvement efforts; (b) senior managers actively supported QM efforts and appropriately responded to QM results; and (c) the system was in compliance with VHA directives, appropriate accreditation standards, and Federal and local regulations. To evaluate QM processes, we interviewed senior managers and reviewed the self-assessment completed by QM staff regarding compliance with QM requirements. We evaluated documents related to the functioning of the Performance Improvement Board as well as other relevant QM documents and committee minutes.

We found that system managers supported QM efforts and that the system adequately monitored credentialing and privileging, patient complaints, national patient safety goals, review of resuscitation and outcomes, and system

redesign/patient flow. However, we identified several program areas that needed strengthening.

Adverse Event Disclosure. Some elements of the system's disclosure policy did not comply with VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, issued October 27, 2005. The system did not consistently conduct appropriate clinical disclosures or evaluate events for possible disclosure, as required. Clinical disclosure is an informal process to discuss harmful events with patients and/or their families; physicians document clinical disclosure in progress notes. Institutional disclosure is a more formal process used in cases of serious injury, death, or potential legal liability and includes an apology and information about compensation and the procedures available to request it. System managers should complete documentation of institutional disclosure using the template in CPRS.

QM staff identified 16 clinical disclosures completed during FY 2007. We found that the institutional disclosure template had been used rather than progress note documentation. The templates documented that the patients and/or family members were informed of their right to file a tort claim or apply for service-connected compensation. This type of disclosure is not appropriate at the clinical level and should only be completed when evaluation for disclosure determines that the system had responsibility for patient harm.

We also identified two cases that should have been evaluated for possible institutional disclosure but were not. Without adequate disclosure processes, managers could not be assured that patients received important medical and legal information needed to make decisions when adverse events occur.

Peer Review. The system's peer review process did not comply with VHA Directive 2004-054, *Peer Review for Quality Management*, issued September 29, 2004. Peer review is a confidential, non-punitive, and systematic process to evaluate quality of care at the individual provider level. The peer review process includes an initial review by a peer of the same discipline within 45 days with subsequent Peer Review Committee (PRC) evaluation and concurrence with the findings within 120 days. We evaluated peer review

activities conducted during FY 2007 and identified the following issues:

- The system initiated 32 peer reviews; however, QM staff were unable to locate 11 peer review files. We could not determine whether the process was completed per policy since these files could not be found.
- Of the remaining 21 cases, we found that 12 initial peer reviews were not completed within the 45-day timeframe and that 19 were not reviewed by the PRC within the 120-day timeframe.
- Managers did not complete quarterly tracking of peer review data (including number of reviews, outcomes by level, and number of changes to outcome levels) nor did they track action items to completion.
- Managers did not review a representative sample¹ of Level 1² peer review cases to evaluate the peer review process and to ensure reliability of the findings.
- The PRC did not consistently meet on a quarterly basis, and minutes were not regularly presented to the Clinical Executive Board (CEB).
- PRC minutes did not consistently reflect the deliberations between the PRC and the provider whose care was under review nor did they reflect the rationale for peer review level changes.

Peer review can result in both immediate and long-term improvements in patient care by revealing areas for improvement in individual providers' practices. Peer reviews should be conducted in accordance with policy to ensure that providers perform according to accepted community standards.

Root Cause Analyses. We found that elements of the RCA process did not comply with VHA guidelines. RCAs are designed to identify and resolve the root cause of system and/or process deficiencies involved in an actual or potential adverse event. VHA Handbook 1050.1, *VHA National Patient Safety Improvement Handbook*, issued January 30, 2002, requires: (1) evaluation of an adverse event to determine if an RCA is required; (2) completion of RCAs within 45 days of the system's identification of need;

¹ Thirty per year or 20 percent, whichever is greater, or all if less than 30.

² Level 1 – Most experienced, competent practitioners would have managed the case similarly.

(3) use of the computerized Patient Safety Information System (PSIS) to guide RCA teams, document RCAs, and communicate results to the National Center for Patient Safety and VISN offices; and (4) implementation of action plans and evaluation of outcomes to ensure that changes have the desired effect.

In FY 2007, the system initiated 17 RCAs (13 individual and 4 aggregate). We found that:

- At the time of our visit, four RCAs were incomplete and 3 months overdue.
- Seven of the completed RCAs had actions that were not tracked to completion and/or outcomes that were not evaluated for effectiveness.
- Fourteen RCAs were not completed within the 45-day timeframe.
- Completed RCAs were not recorded in the PSIS format, resulting in inadequate documentation of important process elements.

In addition, we identified two patient events that required RCAs; however, the system had not planned to initiate them.

During the previous OIG CAP review, we found that aggregate RCAs were not being conducted. We followed up on this condition to determine if corrective actions had been implemented and found this issue to be partially resolved. While aggregate reviews were being conducted, they were not timely.

Without an adequate RCA process, managers could not be assured that quality improvement actions were initiated in a timely manner to prevent recurrence of similar events.

Mortality Review. The mortality review screening process did not result in prompt identification and referral of cases requiring peer review, in accordance with VHA Directive 2005-056, *Mortality Assessment*, issued December 1, 2005. In addition, mortality data was not adequately analyzed to identify unusual trends and was not discussed in a regular forum. We reviewed the mortality log for FY 2007 and found that 9 of 10 cases identified by QM staff as requiring peer review had not been referred. Since deaths were not referred for peer review and data was not adequately

evaluated and discussed, managers could miss opportunities to improve quality of care and patient safety.

Utilization Management. The system's UM program did not include all elements required by VHA Directive 2005-009, *Utilization Management*, issued March 7, 2005. We found that the UM program did not:

- Include formal designation and training of physician advisors.
- Include an analysis of physician approval and/or denial for patients not meeting criteria during the first level of review.
- Identify areas needing improvement, implement corrective actions, or evaluate the effectiveness of actions.
- Evaluate inter-rater reliability of clinical reviews.

The Chief of Staff formally appointed the physician advisors while we were onsite. Without a comprehensive UM program, managers could not be assured that resources were utilized appropriately.

Data Trending, Analysis, and Reporting. The system did not consistently trend, analyze, and report information related to high-risk processes, as required by system policy and The Joint Commission (JC).³ The JC requires data aggregation and analysis to identify patterns and trends and to determine variability or unacceptable levels of performance. System policy requires reporting of data to the CEB for review, analysis of data, and action, as appropriate. The minutes of the Surgical Case Review Committee, the Medical Record Review Committee, and the Blood Bank and Transfusion Committee did not contain trending or analysis of high-risk processes. The CEB minutes did not reflect consistent oversight of these mandatory review areas. Without appropriate data trending analysis, managers could be not assured that patients received appropriate care or that performance improvement activities were initiated when indicated.

³ The Joint Commission was formerly the "Joint Commission on Accreditation of Healthcare Organizations," also known as JCAHO.

- Recommendation 1** We recommended that the Acting VISN Director ensure that the System Director requires evaluation and disclosure of adverse events in accordance with VHA policy.
- Recommendation 2** We recommended that the Acting VISN Director ensure that the System Director requires the peer review process to comply with system and VHA policy.
- Recommendation 3** We recommended that the Acting VISN Director ensure that the System Director requires completion of the RCA process in accordance with VHA policy.
- Recommendation 4** We recommended that the Acting VISN Director ensure that the System Director requires the mortality review process to comply with VHA policy.
- Recommendation 5** We recommended that the Acting VISN Director ensure that the System Director requires the UM program to comply with VHA policy.
- Recommendation 6** We recommended that the Acting VISN Director ensure that the System Director requires high-risk area reviews and oversight to comply with system and VHA policy.

The Acting VISN and System Directors agreed with the findings and recommendations and submitted the following implementation plans.

The clinical disclosure template was modified and made available to providers. Access to the institutional disclosure template has been restricted. Education on use of the templates has been initiated. All adverse events will be reported to the Patient Safety Manager and evaluated for possible disclosure.

All files for cases requiring peer review that were missing during the OIG CAP review have been located, and the cases are appropriately closed. The PRC now meets quarterly and conducts all required reviews. A new process for assignment has substantially improved the timeliness of the review process.

The Patient Safety Program was realigned and strengthened. Use of a tracking mechanism has greatly improved the timeliness of the RCA process, and the

aggregate reviews are on schedule. RCAs were chartered for the two events identified by the OIG.

The required mortality screening criteria were added to the database template to allow for the identification of each death that requires peer review. Aggregate data is trended and reported to the CEB.

The Chief of Staff appointed five physician advisors to support the UM program and scheduled training for them. Data is aggregated, analyzed, and presented to the CEB monthly. A process for evaluating inter-rater reliability will be implemented.

Data analysis training has been scheduled, and priority will be given to staff involved in reviews of high-risk areas. The system plans to purchase software to facilitate data analysis. Data is being collected, analyzed, and reported to the CEB.

The implementation plans are acceptable, and we will follow up on proposed actions until they are completed.

Environment of Care

The purpose of this review was to determine whether the system had a comprehensive EOC program that complied with VHA policy, Occupational Safety and Health Administration regulations, JC standards, and NFPA codes. We inspected 14 clinical areas (including both long-term care units, the locked psychiatric unit, the spinal cord injury unit, the medical intensive care unit, radiology, the operating room, outpatient clinics, and the outpatient pharmacy) in the system's medical center for cleanliness, safety, privacy, infection control, and general maintenance. We did not inspect the system's CBOCs. We reviewed documentation for both the EOC Committee and the Infection Control Committee.

Our inspection revealed that the system's medical center generally maintained a safe and clean environment. Infection control clinicians monitored exposures and infections appropriately. However, we identified conditions related to patient safety, cleanliness and maintenance, oversight, and information security that required management attention.

Patient Safety. We noted the following patient safety concerns:

- Supplies were stored on top shelves within 13 inches of the ceiling tiles in the outpatient pharmacy. The NFPA requires that shelf storage be no closer than 18 inches from the ceiling to prevent obstructing the full distribution of water from the sprinkler heads.
- Two fire egress doors located at the ends of corridors in the NHCU had perimeter gaps between the door and frame in excess of the NFPA standard of one-eighth inch.⁴ Maintaining the one-eighth inch perimeter gap prevents the spread of smoke, poisonous gases, and fire outside of the doors.
- Documentation of all scheduled PMIs was incomplete for five of the seven (71 percent) total pieces of equipment inspected in the NHCU and operating room. Therefore, we could not verify that all PMIs were completed per manufacturer requirements.⁵ This issue was also identified during the July 2007 JC accreditation survey.
- A housekeeping storage closet containing hazardous chemicals was unattended, unsecured, and accessible to patients on the locked inpatient psychiatry unit. The closet door was held open by a housekeeping cart. The housekeeping employee was away from the unit for approximately 30 minutes.
- The shower curtains and hangers on the inpatient psychiatry unit posed a risk of suicide by hanging due to their ability to sustain a distributed weight load. Because clinical managers decided to remove the shower curtains and hangers, we made no recommendations.

Managers should continually assess the patient environment to identify potential hazards. Without mitigation, these conditions compromise patient safety.

Facility Cleanliness and Maintenance. We found four outpatient clinic (OPC) public bathrooms in need of cleaning. We observed paper and other debris on the floors, dirty shoe prints on wet floor surfaces, and what appeared to be urine on the floors adjacent to the urinals and toilets.

In addition, we found that there were soiled, water-damaged, or missing ceiling tiles and corroded ceiling tile grid systems in patient rooms on some of the medical and surgical wards.

⁴ NFPA 80: *Standard for Fire Doors and Other Opening Protectives.*

⁵ JC EOC standards for medical equipment maintenance, testing, and documentation.

The stains and damage indicated that the tiles and grids were overdue for replacement.

Managers are required to provide patients, visitors, and staff with a safe and sanitary environment. Public bathrooms and interior surfaces that have not been adequately cleaned and maintained are safety and infection control hazards.

Oversight. The EOC Committee did not monitor results of ILSM assessments, quarterly fire drills, fire extinguisher inspections, or fire sprinkler and smoke detector system testing, as required by JC Leadership standards. Documentation showed that these required safety reviews were conducted and analyzed by the system's Safety Officer, and the results were reported to the system Director. However, these results were not sent to the EOC Committee for review and documentation in the minutes.

Without oversight by the EOC Committee, managers could not be assured that safety issues were reported to the system's governing body and adequately resolved.

Security of Confidential Patient Information. We found six unsecured and unattended computers in the OPC examination rooms that were displaying confidential patient information. Doors to three of the rooms were open to the hallway, leaving the information exposed to public view. Doors to the other three rooms were closed but unlocked. The Health Insurance Portability and Accountability Act, JC standards, and VHA policy require that the confidentiality of patient information be protected at all times. Managers took appropriate corrective actions while we were onsite. We made no recommendations.

Recommendation 7 We recommended that the Acting VISN Director ensure that the System Director requires that supplies and materials are stored in accordance with NFPA codes.

Recommendation 8 We recommended that the Acting VISN Director ensure that the System Director requires that the two fire egress doors in the NHCU are repaired or replaced.

Recommendation 9 We recommended that the Acting VISN Director ensure that the System Director requires that PMIs are appropriately completed and documented.

Recommendation 10 We recommended that the Acting VISN Director ensure that the System Director requires that housekeeping closets containing hazardous chemicals are secured when unattended.

Recommendation 11 We recommended that the Acting VISN Director ensure that the System Director requires that high-volume public bathrooms are cleaned frequently enough to maintain a safe and hygienic environment.

Recommendation 12 We recommended that the Acting VISN Director ensure that the System Director requires that ceiling tiles and ceiling tile grids are cleaned and replaced, as needed.

Recommendation 13 We recommended that the Acting VISN Director ensure that the System Director requires that ILSM assessments and fire safety inspection data are reported to and reviewed by the EOC Committee.

The Acting VISN and Medical Center Directors agreed with the findings and recommendations and submitted the following implementation plans.

The shelf storage deficiency identified during the OIG CAP visit was corrected. The Safety Officer will remind staff of the minimum distance requirement for supplies and materials storage in a quarterly message. Compliance will be monitored during weekly EOC rounds. We consider this issue closed.

The NHCU fire egress doors were repaired. Perimeter gaps are checked during weekly EOC rounds and during quarterly smoke barrier door inspections. We consider this issue closed.

PMI electronic entries are now done the same day that the equipment is serviced. The system's policy for new equipment was changed to reflect that PMI electronic entries are required before medical equipment units are taken out of the biomedical shop to the services. The biomedical supervisor is monitoring compliance weekly.

Standard operating procedure regarding securing housekeeping closets was reinforced to personnel assigned to the unit where the deficiency was found. Compliance is

monitored during weekly EOC rounds. We consider this issue closed.

The contractor revised the daily cleaning schedule to ensure compliance with contract terms and conditions. Weekly quality control inspections will be conducted to assure compliance.

The ceiling tile and grid deficiencies identified during the OIG CAP visit were corrected. Monitoring is occurring during weekly EOC rounds. We consider this issue closed.

A summary of the EOC Safety Officer's ILSM review, fire safety action plans, and documentation of resolution will now be part of EOC Committee minutes instead of attachments to the minutes.

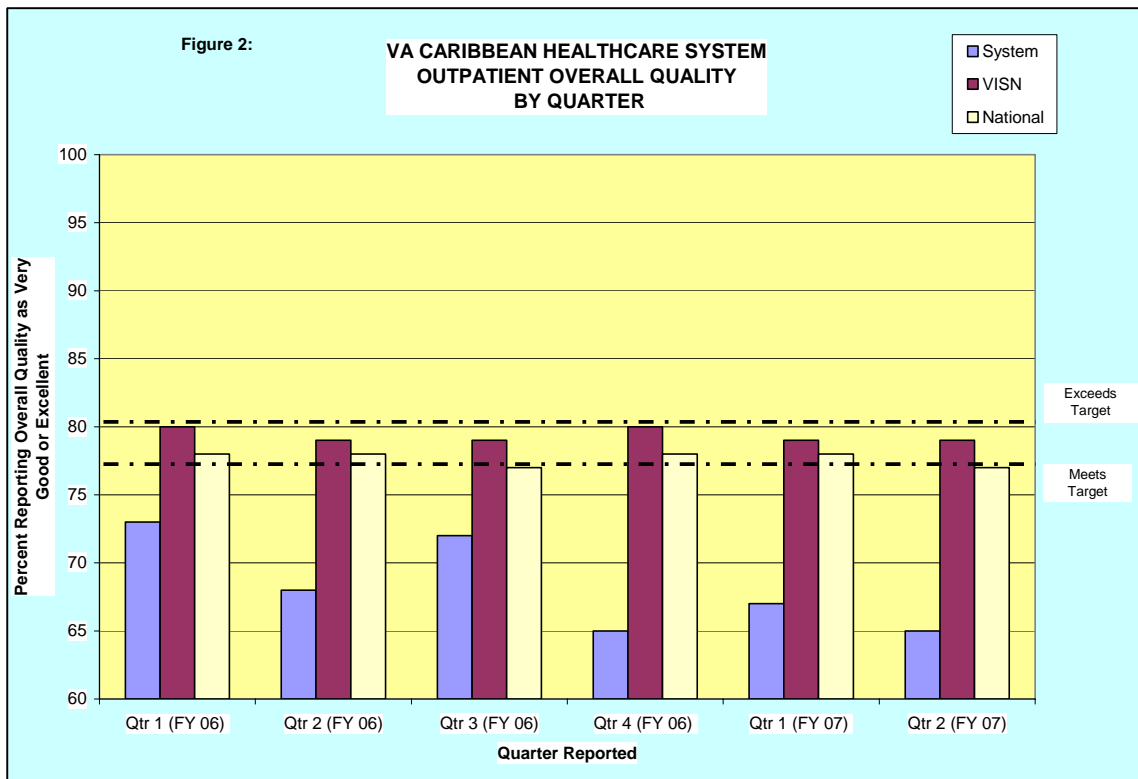
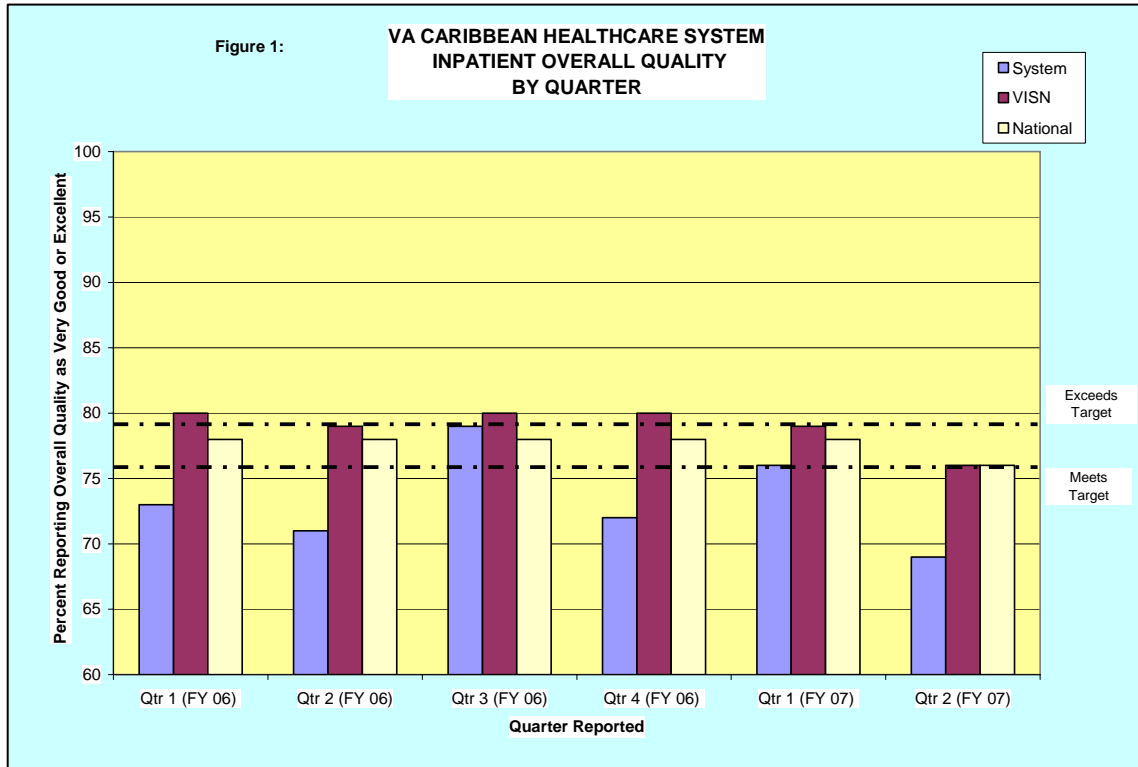
The implementation plans are acceptable, and we consider Recommendations 7, 8, 10, and 12 closed. We will follow up on the remaining proposed actions until they are completed.

Patient Satisfaction

The Survey of Healthcare Experiences of Patients (SHEP) is aimed at capturing patient perceptions of care in 12 service areas, including access to care, coordination of care, and courtesy. VHA relies on the Office of Quality and Performance's analysis of the survey data to improve the quality of care delivered to patients.

The purpose of this review was to assess the extent that VHA medical centers use SHEP data to improve patient care, treatment, and services. VHA's Executive Career Field Performance Plan states that at least 76 percent of inpatients discharged during a specified date range and 77 percent of outpatients treated will report the overall quality of their experiences as "very good" or "excellent." Facilities are expected to address areas in which they are underperforming.

The graphs on the next page show the system's performance in relation to national and VISN performance. Figure 1 shows the system's SHEP performance measure (PM) results for inpatients. Figure 2 shows the system's SHEP PM results for outpatients.



The system's outpatient satisfaction scores have remained below the established target for the last 6 quarters of available data. Inpatient scores have only met the established target in 2 of the last 6 quarters. The system Director has approved a plan to have a consultant with customer service expertise visit the system's medical center to assess their unique problems.

Inpatient Satisfaction. Scores reflecting inpatients' satisfaction were significantly below national averages. To improve satisfaction scores, managers implemented "Day-Before-Discharge" discharge planning. Data is now being collected and will be analyzed to determine if the protocol decreases discharge delays and improves satisfaction with the discharge process.

Outpatient Satisfaction. Access is a primary concern for outpatients. Unavailability of parking and lengthy provider waiting times are the most common complaints. Massive construction projects and a fire in the new parking deck further decreased available parking space at the system's medical center. To increase patient parking spaces, employees were provided with remote parking and shuttle service to the system's medical center and with financial incentives to commute to work via the light rail train.

The Customer Service Committee has goals for FY 2008 that include increasing outpatient overall satisfaction by 5 to 10 percent and reducing access and timeliness complaints by 5 percent. The action plan includes creation of information desks in the main lobby and pharmacy waiting areas and implementation of a "greeters program" at the main entrances to the system's medical center. We suggested that they reinstitute the random unannounced monitors of provider waiting times that were conducted for several months in 2006.

Customer Service Training. Although system policy requires all employees to obtain 1 hour of customer service training every 3 years, we found that 7 percent of system employees had not completed this mandatory training. Veterans Canteen Service employees have regular contact with patients and their families, yet less than 44 percent had completed this training requirement in the past 3 years. In addition, VISN 8 requires that new employees attend a one-time, 6-hour class entitled "Treating Veterans with CARE" within 90 days after their initial appointment. We

reviewed a sample of 53 eligible employees who received new employee orientation in February or March 2007 and found that only 7 of 53 (13 percent) had attended this class. Of those seven, only four received the training within 90 days of their appointment.

Managers were taking actions to improve patient satisfaction scores. However, since the system's most recent inpatient and outpatient SHEP scores remain significantly below targets, managers should enforce customer service training requirements. Enhanced customer service could improve patient satisfaction.

Recommendation 14

We recommended that the Acting VISN Director ensure that the System Director monitors completion of mandatory customer service training.

The Acting VISN and System Directors agreed with the finding and recommendation. The Customer Service Manager will provide training at each service's staff meeting. The Customer Service Committee has planned monthly "Treating Veterans with CARE" training for new employees, and the Customer Service Manager will monitor attendance. The implementation plans are acceptable, and we will follow up on the proposed actions until they are completed.

Review Activities Without Recommendations

Computerized Patient Record System Business Rules

Business rules define which groups or individuals are allowed to edit, amend, or delete documentation in electronic medical records. The health record, as defined in VHA Handbook 1907.01, *Health Information Management and Health Records*, issued August 25, 2006, includes the electronic and paper medical record. It includes items, such as physician orders, progress notes, and examination and test results. In general, once notes are signed, they should not be altered.

On October 20, 2004, the VHA Office of Information (OI) sent software informational patch USR*1*26 to all medical centers with instructions to assure that business rules complied with VHA regulations. The guidance cautioned that "the practice of editing a document that was signed by the author might have a patient safety implication and should not be allowed." In January 2006, the OIG identified a facility where progress notes could be improperly altered and recommended that VHA address the issue on a national

basis. On June 7, 2006, VHA issued a memorandum to VISN Directors instructing all VA medical centers to comply with the informational patch sent in October 2004.

We reviewed the system's business rules and found that all rules were in compliance with VHA policy. We made no recommendations.

Surgical Care Improvement Project

The purpose of the review was to determine if clinical managers implemented strategies to prevent or reduce the incidence of surgical infections for patients having major surgical procedures. Surgical infections present significant patient safety risks and contribute to increased post-operative complications, mortality rates, and health care costs.

We evaluated the following VHA PM indicators:

- Timely administration of prophylactic (preventive) antibiotics to achieve therapeutic serum and tissue antimicrobial drug levels throughout the operation. Clinicians should administer antibiotics within 1–2 hours prior to the first surgical incision.
- Timely discontinuation of prophylactic antibiotics to reduce risk of the development of antimicrobial resistant organisms. Clinicians should discontinue antibiotics within 24–48 hours after surgery.
- Controlled blood glucose levels for cardiac surgery, which should be maintained below 200 milligrams/deciliter for the first 2 days post-operative. Elevated levels impair the body's ability to fight infection.
- Controlled core body temperature for colorectal surgery, which should be maintained at greater than or equal to 36 degrees Centigrade or 96.8 degrees Fahrenheit immediately after surgery. Decreased core body temperature is associated with impaired wound healing.

VHA set target PM scores for each of the above indicators. To receive fully satisfactory ratings, a facility must achieve the following scores:

Performance Measure	FY 2007 Target Score
Timely antibiotic administration	90 percent
Timely antibiotic discontinuation	87 percent
Controlled blood glucose – cardiac surgery	90 percent
Controlled body temperature – colorectal surgery	70 percent

At the time of our site visit, the system's most recent PM scores for antibiotic administration and controlled body temperature met targets.

The system did not meet the targets for antibiotic discontinuation and blood glucose control after cardiac surgery. System managers had initiated the following strategies to improve PM scores that fell below the established targets:

- Implemented a protocol for antibiotic discontinuation.
- Hired a full time surgical cardiovascular intensivist to monitor post-operative care.
- Implemented a protocol for intravenous insulin infusion to ensure control of blood glucose levels.
- Developed a template for post-anesthesia care documentation in CPRS.

We reviewed the medical records of 30 patients who had cardiac, colorectal, vascular, or orthopedic (knee and hip replacement) surgery during the 3rd quarter of FY 2007. We found timely administration of antibiotics in all 30 surgical cases and timely discontinuation of antibiotics in 28 of 30 cases. We found blood glucose levels within acceptable ranges in eight of eight cardiac surgery cases and body temperature adequately controlled in six of seven colorectal surgery cases.

Overall, we found that the system had implemented appropriate actions to improve performance. We made no recommendations.

Acting VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: January 24, 2008

From: Acting Director, VA Sunshine Healthcare Network (10N8)

Subject: Combined Assessment Program Review of the VA
Caribbean Healthcare System, San Juan, Puerto Rico

To: Associate Director, Atlanta Office of Healthcare Inspections
(54AT)

Director, Management Review Service (10B5)

1. I have reviewed and concur with the findings and recommendations in the report of the Combined Assessment Program Review of the VA Caribbean Healthcare System, San Juan, Puerto Rico.
2. Corrective action plans have been established with planned completion dates, as detailed in the attached report.

(original signed by:)

Charleen R. Szabo

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: January 18, 2008
From: Director, VA Caribbean Healthcare System (672/00)
Subject: Combined Assessment Program Review of the VA Caribbean Healthcare System, San Juan, Puerto Rico
To: Acting Director, VA Sunshine Healthcare Network (10N8)

1. We thank you for allowing us the opportunity to review and respond to the subject report.
2. We concur with the conclusions and recommendations presented by the Office of the Inspector General. We present you the plan of action designed to correct those areas where we were provided with recommendations.

(original signed by:)

RAFAEL E. RAMIREZ, MD, FACP

Comments to Office of Inspector General's Report

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

OIG Recommendations

Recommendation 1. We recommended that the Acting VISN Director ensure that the System Director requires evaluation and disclosure of adverse events in accordance with VHA policy.

Concur

Target Date: Corrected January 15, 2008

The process for the clinical disclosure of adverse events, the informal process of informing patients or their representatives of harmful adverse events related to care, is documented by providers responsible for the patient's care. A CPRS template entitled "Disclosure of Events" has been modified and made available to providers for such documentation. The template excludes any information about institutional disclosure.

The process for institutional disclosure of adverse events is necessary in circumstances resulting in serious injury or death to patients, or those involving potential legal liability. This formal process includes the patient or representative, and any family member designated by the patient or representative, meeting with medical center leaders and others, as appropriate. During the meeting, an apology is made, and information about compensation, and procedures available to request compensation, is provided, when appropriate. As required, the medical center utilizes the CPRS template, "Institutional Disclosure of Events," for the documentation of this process and its outcomes. As a change to our process, access to the use of this template has been restricted to the Chief of Staff, the Director, and a group of staff members of the facility.

Clinical staff education regarding clinical and/or institutional disclosure (e.g., understanding the different purposes, how to identify, and so forth) has been initiated.

All adverse events will be reported to the Patient Safety Manager (PSM) and evaluated for possible disclosure. If disclosure is found to be appropriate, the PSM will notify the Director, and all steps for disclosure will be taken per VHA Directive 2005-049. The PSM will be responsible to track the disclosures and to report all disclosures to Leadership.

The Patient Safety Manager has been instructed to document actions for Institutional disclosures as part of the Adverse Event Issue Brief and/or as part of the RCA recommendations.

Recommendation 2. We recommended that the Acting VISN Director ensure that the System Director requires the peer review process to comply with system and VHA policy.

Concur

Target Date: December 31, 2007

All cases requiring peer review that were missing during the OIG CAP Review have been located and are appropriately closed.

The Peer Review Subcommittee will meet no less than quarterly. The minutes reflect discussions of the cases and the deliberations between the provider and the PRC and will be presented to CEB no less than quarterly. Actions are being tracked to ascertain closure. Effective December 2007, the minutes are being routed through the Chief of Staff and the Director for concurrence.

Since October 2007, the PRC has discussed a total of 12 cases, of which 4 were carried over from FYs 2006 and 2007. For all eight (8) FY 2008 cases referred to peer review, the initial reviews were performed within the 45-day timeframe. The cases are scheduled to be reviewed and closed by the PRC within the 120-day timeframe.

The Quality Management Office initiated a new process of electronically notifying service chiefs for assignment of peer reviewers and for receipt of their responses. This has substantially improved the timeliness of the review process.

In lieu of reviewing a representative sampling of Level 1 determinations, 100 percent of such cases are reviewed by the designated committee member (without involvement in the case) and are discussed at the Peer Review Subcommittee Meeting.

The PRC conducts quarterly aggregation of the committee findings. The data informs the number of reviews and the outcomes of review by Level 1, Level 2, or Level 3. Data management also demonstrates the number of changes made from one level to a different level (higher or lower) during the review process and follow-up on action items and recommendations by the PRC that result from completed protected peer review.

Recommendation 3. We recommended that the Acting VISN Director ensure that the System Director requires completion of the RCA process in accordance with VHA policy.

Concur

Target Date: March 31, 2008

During the first quarter FY 2008, a total of six individual RCAs were initiated. Of those, four (4) have been completed within the 45 days. Of the two remaining, both are still within the 45-day timeframe.

The medical center developed and utilizes a tracking mechanism table, which includes the following data elements: RCA #, Event Date, Facility Awareness Date, Due Date, Date Completed, and Calculation of Total Days for Completion. The use of this tracking mechanism has greatly improved the timeliness of the RCA process, as demonstrated above.

In December 2007, the OIG notified the VA Caribbean Healthcare System of two patient events they identified that required RCAs. The RCAs were chartered on 12/08/2007. Both cases are on target for timeliness and are scheduled to be presented for the Director's approval during the week of January 14, 2008.

A calendar has been created to track the dates that actions are due to be completed from the assigned services. Documentation of those actions is tracked by the Patient Safety Manager and entered into SPOT Software. Overall performance is reported to the CEB through the Performance Improvement Board.

Since October 2007, the facility Patient Safety Program has been realigned and restructured and strengthened with additional FTE.

The presentation of the findings and recommendations for the Falls Aggregate Review that was due December 1, 2007, has been scheduled for the week of January 28, 2008. The Missing Patients Aggregate Review scheduled for the 2nd quarter is in progress and on track for completion by March 1, 2008.

Recommendation 4. We recommended that the Acting VISN Director ensure that the System Director requires the mortality review process to comply with VHA policy.

Concur

Target Date: February 6, 2008

The Quality Management staff at the medical center screen all deaths against the death review criteria. On October 2007, the database template was modified to include the required Mortality Screening Criteria. This allows for the identification of each death that requires peer review. Each case meeting the screening criteria is referred to the service chief for assignment of a peer reviewer.

Mortality Review data will be reported to CEB on a quarterly basis starting February 6, 2008. The aggregate data is trended/plotted (by ward, service, and tour of duty [and provider when a specific provider can be linked to the care of specific patients]) and will be reported to the CEB. The CEB minutes will document discussion of trends, identification of any unusual or concerning patterns, and determination of the need for action and/or follow-up.

Recommendation 5. We recommended that the Acting VISN Director ensure that the System Director requires the UM program comply with VHA policy.

Concur

Target Date: February 1, 2008

The Chief of Staff appointed five (5) Physician Advisors from Medicine, Surgery, Psychiatry, PM&RS, and SCI Services to support the UM Program. The Physician Advisors training has been scheduled for January 25, 2008.

UR Specialists will perform admission and continued stay reviews, as per UM policy. Cases not meeting criteria will be reported to a second-level reviewer (Specialist or Attending Physician) for further deliberation. Physician Advisors, as part of the third-level review process, provide recommendations to the UR staff. The form for InterQual (Secondary Revision) will be used to record this information.

Data on physician approval and/or denial for patients not meeting criteria during first-level review is aggregated and analyzed by service (Medicine/Surgery/Psychiatry) and presented to the CEB through the UM and Discharge Planning Committee on a monthly basis. Areas needing improvement will be identified, corrective actions will be implemented, and the effectiveness of these actions will be evaluated on an ongoing basis.

A process for evaluating inter-rater reliability of clinical reviews will be implemented as follows:

- Supervisor will select five (5) cases at random for each UM Specialist on a monthly basis.

- Each UM Specialist will be assigned five cases other than his/her own for UM-related review of the last 5 days of each case. The percent (%) of concurrence for each reviewer will be calculated and feedback will be provided.

Recommendation 6. We recommended that the Acting VISN Director ensure that the System Director requires high-risk area reviews and oversight to comply with system and VHA policy.

Concur

Target Date: March 14, 2008

Since December 2007, data has been aggregated for the Medication Utilization Evaluation (MUE) process. This is being presented to the MUE Subcommittee, which in turn presents it to the P&T Committee for analysis.

Data analysis training, presented by the VHA Employee Education System (EES) Performance Improvement and Data Management Consultant, has been scheduled for February 26–28, 2008, at VACHCS. Priority will be given to staff involved in reviews of high-risk areas. The training will emphasize data elements, data collection, data aggregation, data trending, and data analysis. Content will also include tools and techniques to optimize data display and data analysis processes, including information about excessive variability of a process or unacceptable performance as compared to a target.

Request has been submitted to IRM for purchasing of the QI Macros Software. This software will facilitate data analysis.

Data is collected and analyzed as part of the Medical Record Review, Operative and Invasive Procedure Review, and Blood Utilization Review processes, and summarization is reported up to the CEB. National Surgical Quality Improvement Program data and reports are being added to the agenda for the CEB on a periodic basis.

Recommendation 7. We recommended that the Acting VISN Director ensure that the System Director requires that supplies and materials are stored in accordance with NFPA codes.

Concur

Target Date: Corrected October 19, 2007

The area identified during OIG CAP visit was corrected. The Safety Officer will remind VACHS staff of the minimum distance requirement for supplies and materials storage by providing a quarterly electronic

message to all users. This message will also include the most common Safety Inspection findings, and they will be discussed during the staff annual General Safety and Fire Protection Training.

To ascertain compliance, the scheduled weekly Environment of Care (EOC) Rounds that are conducted by a multidisciplinary team will monitor that supplies and materials are stored no closer than 18 inches from sprinkler heads, as required by NFPA Standards.

Recommendation 8. We recommended that the Acting VISN Director ensure that the System Director requires that the two fire egress doors in the NHCU are repaired or replaced.

Concur

Target Date: Corrected October 19, 2007

The facility Safety Officer certified that the NHCU fire egress doors were inspected and repaired, ensuring perimeter gaps did not exceed the NFPA Standard of one-eighth of an inch.

In addition, gaps are checked during weekly scheduled EOC rounds, and during scheduled quarterly smoke barrier door inspections.

Recommendation 9. We recommended that the Acting VISN Director ensure that the System Director requires that PMIs are appropriately completed and documented.

Concur

Target Date: Corrected October 19, 2007

Fiscal year (FY) 2007 Annual Assessment Medical Equipment Report shows 91.9 percent compliance, exceeding the 90 percent established by the facility Medical Equipment Management Plan for non-life support equipment, with Planned Maintenance of 1,670 units. Of the five units reviewed and found out of compliance, three (3) were newly acquired units. These three (3) units were already inspected, and the documentation of the performed testing was included in the paper record at the Biomedical Shop but not yet entered in the electronic equipment management system. These new units have been entered in the system for programming the scheduled maintenance. The other two units were non-life support equipment, but the 90 percent scheduled maintenance target for non-life support equipment was exceeded, as stated above.

To ascertain that all documentation is up-to-date, PMIs electronic entries are done within the same date of the service. The New Equipment Acceptance Testing and Check-in Policy (Facility Management Service

Policy Memo 07-04) was changed to reflect that PMI electronic entries are required before the medical equipment unit is taken out of the Biomedical Shop to the corresponding service or SPD.

The Biomedical supervisor is monitoring compliance weekly by verifying the electronic record for new equipment.

Recommendation 10. We recommended that the Acting VISN Director ensure that the System Director requires that housekeeping closets containing hazardous chemicals are secured when unattended.

Concur

Target Date: Corrected October 16, 2007

Housekeeping closets containing hazardous chemicals are required to be secured when unattended. Standard operating procedure was reinforced to personnel assigned to this area. General Safety Training, to include security of chemicals and equipment, is included in the yearly Housekeeping Personnel Education Plan. In addition, staff is required to have yearly mandatory General Safety and Fire Protection Training.

For ongoing monitoring of compliance, housekeeping closets are checked during weekly scheduled EOC rounds. In addition, if a housekeeping closet is noted to be unsecured while unattended, unit managers and staff have been informed to make on-the-spot corrections by immediately contacting the housekeeping supervisor to secure the area.

Recommendation 11. We recommended that the Acting VISN Director ensure that the System Director requires that high-volume public bathrooms are cleaned frequently enough to maintain a safe and hygienic environment.

Concur

Target Date: Corrected October 16, 2007

Contractor was notified and the item reported was corrected. Meeting was held with Contractor, and the Contractor revised their Quality Control Program and daily cleaning schedule to ensure compliance with contract terms and conditions.

This contract is a performance-based contract, and the government will continue monitoring the Contractor to ensure the quality of services is performed in accordance with contract terms and conditions.

The Chief, Environmental Program, the designated COTR, will monitor this action. Weekly Quality Control Inspection will be conducted to assure compliance.

If the Contractor is found to be in non-compliance, re-performance will be requested and if continued non-compliance, the Contracting Officer will be informed and necessary action taken through written notice.

Recommendation 12. We recommended that the Acting VISN Director ensure that the System Director requires that ceiling tiles and ceiling tile grids are cleaned and replaced as needed.

Concur

Target Date: Corrected October 19, 2007

The areas identified during OIG CAP visit were corrected. Maintenance is being conducted, as required, on the replacement of ceiling tiles and the restoration of the ceiling tile grid system (painting). However, the ceiling tile grid system will not be replaced at this time. All patients and staff currently in the main tower will be moved to the new South Bed Tower (first major project). This first major project is scheduled to be completed within the next 2 years. The scope of the second major project includes dismantling the main tower.

Monitoring that all ceiling tiles are in place, and that damaged/stained ceiling tiles are replaced as needed, is being accomplished during weekly EOC rounds and other general facility rounds.

Recommendation 13. We recommended that the Acting VISN Director ensure that the System Director requires that ILSM assessments and fire safety inspection data are reported to and reviewed by the EOC Committee.

Concur

Target Date: January 25, 2008

The EOC Safety Officer is monitoring the results of the ILSM assessments, quarterly fire drills, fire extinguisher inspections, and fire sprinkler and smoke detector system testing, as required by Joint Commission Leadership standards. These results were and continue to be reported to the EOC Committee, as specified in the EOC review schedule, Attachment B of the EOC Committee Center Memorandum.

Reports are included as attachments to the minutes; however, effective with the January 25, 2008, EOC Committee Meeting, a summary of discussion, including any action plans, appropriate target dates, need for

follow-up, and documentation of completion/resolution of actions, will be documented as part of the minutes.

Recommendation 14. We recommended that the Acting VISN Director ensure that the System Director monitors completion of mandatory customer service training.

Concur

Target Date: Corrected January 15, 2008

As of January 15, 2008, the Veterans Canteen Service is 100 percent compliant with the Customer Service Training.

To ascertain compliance with the mandatory training requirement, the VACHS's Customer Service Manager initiated an educational plan to cover all system services and locations in coordination with Service Chiefs and Supervisors. He will provide the training at each service's staff meetings. The CS manager will report the percentage of compliance with the training at the facility's ELB meetings on a monthly basis. As of December 31, 2007, the mandatory training has been provided to Health Benefits and Administration Service, Physical Medicine and Rehabilitation Service, Veterans Canteen Service, and Human Resources.

The Customer Service Committee has planned monthly Treating Veterans With CARE training for the 1st Thursday of the month. New employees are expected to attend the training. The Human Resources Specialist coordinating new employee orientation will notify each new employee and his/her Service Chief of the date the new employee is scheduled to attend. The Customer Service Program Manager, in coordination with Human Resources, will schedule additional monthly sessions for new employees as needed.

On a monthly basis, the Customer Service Manager will monitor compliance with this requirement by comparing the new employees' attendance list for Treating Veterans With CARE training against the list of all new employees. The Customer Service Manager will reschedule those new employees that have not attended training, notifying the new employee and Service Chief of the training date, and will again verify attendance until the training has been completed.

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