



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

Office of Healthcare Inspections

Report No. 07-03172-114

Combined Assessment Program Review of the VA Boston Healthcare System Boston, Massachusetts



April 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 March 10–14, 2008, the OIG conducted a Combined Assessment Program (CAP) review of the VA Boston Healthcare System (the system), Boston, MA. 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 for 97 system employees. The system is part of Veterans Integrated Service Network (VISN) 1.

Results of the Review

The CAP review covered five operational activities and assessed compliance with recommendations made during our prior CAP review conducted in February 2005. We identified the following organizational strength and reported accomplishment:

- Clinical managers implemented an elective rotation in the system's QM department for medical and surgical residents to give them experiences with improving patient safety and quality of care.

We made recommendations in three of the activities reviewed. For these activities, system managers needed to:

- Appoint controlled substances (CS) inspectors in writing and ensure that appointment letters are retrievable for verification purposes.
- Ensure that CS inspectors validate two CS transfers from one area to another during monthly inspections.
- Ensure that CS inspectors verify that change of shift counts for non-automated dispensing units and weekly inventories of the automated unit are completed during monthly inspections.
- Ensure that CS inspectors reconcile 1 day's dispensing from the pharmacy to the automated unit during monthly inspections.
- Ensure that quarterly CS inspection reports are submitted to the system's Director.
- Ensure that Engineering Service and Safety managers inspect all portable fire extinguishers monthly.

- Ensure that Engineering Service managers inspect the wander alert systems annually and establish a log of maintenance and repairs.
- Review computerized patient record system (CPRS) business rules regularly to ensure compliance with Veterans Health Administration (VHA) regulations and local policy.

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

- QM Program.
- Survey of Healthcare Experiences of Patients (SHEP).

This report was prepared under the direction of Jeanne Martin, Associate Director, Bedford Office of Healthcare Inspections.

Comments

The VISN and System Directors agreed with the CAP review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 13–17, for the full text of the Directors' comments.) We will follow up on the planned 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 provides a broad range of inpatient and outpatient health care services at three divisions in West Roxbury, Jamaica Plain, and Brockton, MA. It also provides outpatient care services at six community based outpatient clinics in Boston, Dorchester, Worcester, Framingham, Lowell, and Quincy, MA. The system is part of VISN 1.

Programs. The West Roxbury division serves as the tertiary inpatient center and is a regional referral center for VISN 1 for inpatient surgery. West Roxbury also has an acute spinal cord injury program. The Jamaica Plain division offers ambulatory surgery and primary care services. The Brockton division provides long-term care, chronic spinal cord injury care, and acute mental health services (including an inpatient psychiatric unit for women and a residential rehabilitative unit for women suffering from both post-traumatic stress disorder and substance abuse). Brockton also offers comprehensive primary care.

Affiliations and Research. The system is affiliated with Boston University's School of Medicine, Harvard Medical School, Tufts University's School of Medicine, and the University of Massachusetts' Medical School. Annually, the system educates more than 1,000 medical and surgical residents. The system also provides training for students in nursing and other health professions, such as social work, psychology, and pharmacy.

The system has a diverse research program with an annual budget of \$44 million. It has approximately 800 projects and 200 investigators. Major areas of research include endocrinology, cardiology and cardiovascular diseases, spinal cord injury, aging, language and memory disorders, hematology, post-traumatic stress disorder, and infectious diseases.

Resources. In fiscal year (FY) 2007, the system's medical care budget totaled over \$42.7 million. FY 2007 staffing was 3,268 full-time employee equivalents (FTE), including 219 physician and 967 nursing FTE.

Workload. During FY 2007, the system treated more than 64,000 unique patients and had 436 operating hospital beds. The FY 2007 inpatient care workload totaled over

11,000 patients, and the average daily census was 342. Outpatient care visits for FY 2007 totaled approximately 628,000.

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.
- Environment of Care (EOC).
- Pharmacy Operations.
- QM Program.
- SHEP.

The review covered system operations for FY 2007 and was done in accordance with OIG standard operating procedures for CAP reviews. We also followed up on recommendations regarding emergency preparedness and pressure ulcer prevention from the prior CAP review of the system (*Combined Assessment Program Review of the VA Boston Healthcare System, Boston, Massachusetts, Report No. 05-00734-67, January 31, 2006*).

During this review, we presented fraud and integrity awareness briefings for 97 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.

Organizational Strength

Resident Rotation in Patient Safety and Quality Improvement

In 2006, the system's clinical managers implemented an elective rotation in the QM department for medical and surgical residents to give them experiences with improving patient safety and quality of care. Managers believe that introducing residents to the importance of patient safety and quality of care principles early in their careers could improve their commitment to these principles throughout their medical practices. During the rotation, residents participate in root cause analyses and committee meetings that focus on patient safety and quality improvement. Managers expanded the rotation from 2 weeks to 4 weeks after the 1st year. This program was highlighted in The Joint Commission's *Perspectives on Patient Safety™* in September 2007.

Results

Review Activities With Recommendations

Pharmacy Operations

The purpose of this review was to evaluate whether VA health care facilities have adequate controls to ensure the security and proper management of CS and the pharmacies' internal physical environments. We also determined whether clinical managers had processes to monitor inpatient and outpatient medication use to avoid polypharmacy in vulnerable populations, such as the elderly and mental health patients.

Pharmacy Controls. We reviewed VHA regulations¹ governing pharmacy and CS security, and we assessed whether the system's policies and processes were consistent with VHA regulations. We reviewed the CS inspection program at the system's main division in West Roxbury, and we inspected inpatient and outpatient pharmacies at the West Roxbury and Brockton divisions for security, EOC, and infection control (IC) issues. In addition, we interviewed appropriate Pharmacy Service and Police and Security Service managers.

The system's policies and processes were effective in ensuring the security of the pharmacies and CS. The CS inspection program complied with many of VHA's inspection procedures, such as ensuring that training requirements for the CS Coordinator and CS inspectors were met. In addition, required monthly inspections at West Roxbury included CS counts in the pharmacy, on inpatient units, in outpatient clinics, and in the animal research laboratory. Monthly inspections verified that pharmacy staff completed 72-hour inventories of CS, and we found that managers reported suspected diversions to the OIG. The pharmacies at the West Roxbury and Brockton divisions were secure, clean, and well maintained. However, we identified areas that would improve controls over the system's pharmacy operations.

VHA regulations require that CS inspectors be appointed in writing by facility directors. We found that 2 of 14 (14 percent) appointment letters for West Roxbury CS inspectors were not available for review. In addition, monthly CS inspection documentation did not confirm that CS inspectors validated that two CS transfers from one area to another or that change of shift counts for non-automated dispensing units were completed, as required by VHA regulations. Also, we could not validate if inspectors confirmed that weekly inventories of the automated medication dispensing unit were completed or if inspectors reconciled 1 day's dispensing activity from the pharmacy to the automated dispensing unit, as required.

VHA regulations also require that quarterly reports be submitted to facility directors, summarizing discrepancies,

¹ VHA Handbook 1108.1, *Controlled Substances (Pharmacy Stock)*, October 4, 2004; VHA Handbook 1108.2, *Inspection of Controlled Substances*, August 29, 2003; VHA Handbook 1108.5, *Outpatient Pharmacy*, May 30, 2006; VHA Handbook 1108.6, *Inpatient Pharmacy*, June 27, 2006.

problematic trends, and potential areas for improvement. We were not provided with documentation to support that quarterly reports were submitted to the system's Director.

Polypharmacy. Pharmacological regimens involving multiple medications are often necessary to prevent and maintain disease states; however, excessive use of medications can result in adverse reactions and increased risks of complications. Polypharmacy is more complex than just the number of drugs that patients are prescribed. The clinical criteria to identify polypharmacy are the use of (a) medications that have no apparent indication, (b) therapeutic equivalents to treat the same illness, (c) medications that interact with other prescribed drugs, (d) inappropriate medication dosages, and (e) medications to treat adverse drug reactions.² Some literature suggests that elderly patients and mental health patients are among the most vulnerable populations for polypharmacy.³ We interviewed pharmacy clinical managers to determine the system's efforts to monitor and avoid inappropriate polypharmacy.

Our review showed that clinical pharmacists identified patients who were prescribed multiple medications, reviewed the patients' medication regimens to avoid complications related to polypharmacy, and advised providers regarding potential polypharmacy complications when appropriate.

Recommendation 1 We recommended that the VISN Director ensure that the System Director appoints all CS inspectors in writing and that appointment letters are retrievable for verification purposes.

Recommendation 2 We recommended that the VISN Director ensure that the System Director requires that CS inspectors validate two CS transfers from one area to another during monthly inspections.

Recommendation 3 We recommended that the VISN Director ensure that the System Director requires that CS inspectors verify that change of shift counts for non-automated dispensing units

² Yvette C. Terrie, BSPHarm, RPh, "Understanding and Managing Polypharmacy in the Elderly," *Pharmacy Times*, December 2004.

³ Terrie, *Pharmacy Times*, December 2004; Vijayalakshmy Patrick, M.D., et al., "Best Practices: An Initiative to Curtail the Use of Antipsychotic Polypharmacy in a State Psychiatric Hospital," *Psychiatric Services*, 57:21-23, January 2006.

and weekly inventories of the automated unit are completed during their monthly inspections.

Recommendation 4 We recommended that the VISN Director ensure that the System Director requires that CS inspectors reconcile 1 day's dispensing activity from the pharmacy to the automated unit during their monthly inspections.

Recommendation 5 We recommended that the VISN Director ensure that the System Director requires that the CS Coordinator submit quarterly reports summarizing discrepancies, problematic trends, and potential areas for improvement.

The VISN and System Directors agreed with the findings and recommendations. They reported that the System Director will appoint new CS inspectors through memorandums, and the CS Coordinator will file the memorandums for verification purposes. The target completion date is June 30, 2008.

The VISN and System Directors also reported that CS checklist forms were amended to include verification of two transfers of CS from one area to another, change of shift CS counts for non-automated dispensing units, weekly inventories of the automated dispensing unit, and reconciliation of 1 day's dispensing of CS from the pharmacy. Additionally, the CS Coordinator will begin submitting quarterly reports to the System Director by April 30, 2008. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

Environment of Care

VHA regulations require that health care facilities provide clean and safe environments in all patient care areas and establish comprehensive EOC programs that fully meet National Center for Patient Safety, Occupational Safety and Health Administration, and Joint Commission standards. We inspected patient care areas at all three divisions for cleanliness, safety, IC processes, and general maintenance.

Environment of Care Inspections. At the West Roxbury division, we inspected the following areas: (a) acute medicine and rehabilitation, (b) acute surgery and neurology, (c) acute spinal cord injury, (d) an acute medicine unit, (e) a surgery unit, (f) an intensive care unit, (g) the progressive care unit, and (h) the spinal cord injury patient apartment. At the Brockton division, we inspected two acute psychiatry units, two chronic psychiatry units, a transitional care unit,

and a nursing home care unit. At the Jamaica Plain division, we inspected the Substance Abuse Residential Rehabilitation Program area, the dialysis unit, and the urgent care area. We also inspected primary care, hematology/oncology, and dermatology clinic areas.

The system maintained generally clean and safe environments at all divisions. The IC program monitored and reported data to clinicians, and the data were used to implement quality of care improvements. Risk assessments complied with VHA standards. Additionally, managers on the locked acute inpatient psychiatric units complied with safety regulations and trained staff to identify environmental hazards. However, we identified issues that needed management attention.

In the spinal cord injury patient apartment at the West Roxbury division, we found that two fire extinguishers were not checked monthly, as required by National Fire Protection Association (NFPA) Code 10. In addition, Engineering Service could not provide documentation that the wander alert systems used at the West Roxbury and Brockton divisions were inspected annually or that the service had established a maintenance and repair log, as required by the system's policy.⁴

Emergency Preparedness. As part of the EOC review, we assessed compliance with Emergency Preparedness Program recommendations from the prior CAP review. In that report, we recommended that all research areas be secured, all employees comply with VA security directives, and training in the use of personal protective equipment (PPE) be provided to employees. We visited the research building cited in the report and found that all entrances and exit doors were secured and monitored by key card access. A review of five employee training records showed that managers provided the required PPE training. These actions addressed the recommendations from the previous CAP report, and we consider these issues closed.

Recommendation 6

We recommended that the VISN Director ensure that the System Director requires monthly inspections of all portable fire extinguishers, as required by NFPA Code 10.

⁴ Patient Care Memorandum 118-007-LM, *Wander Alert Guidelines*, February 2007.

Recommendation 7

We recommended that the VISN Director ensure that the System Director requires that Engineering Service inspect the wander alert systems annually and establish a maintenance and repair log.

The VISN and System Directors agreed with the findings and recommendations. They reported that Safety Office employees will perform inspections to validate the current inventory of fire extinguishers and that this inventory will be used for conducting monthly inspections. The Safety Officer will also conduct weekly random checks of fire extinguishers at each division to verify that inspections are up to date.

The VISN and System Directors also reported that Engineering Service will list the wander alert systems in the equipment inventory database for yearly preventative maintenance inspections. Engineering managers will complete the 2008 annual inspection and record the completed inspection in the database by April 30, 2008. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

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 regulations,⁵ includes both the electronic and paper medical record. It includes items, such as physician orders, progress notes, and examination and test results. In general, once progress 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 and systems 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, 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 and systems to comply with the informational patch sent in October 2004.

⁵ VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006.

We reviewed VHA and system information and technology policies and interviewed Clinical Information Systems staff. We determined that a total of seven business rules (four document specific rules, one user class rule, and two rules related to user roles) needed to be removed to limit deletion of notes to the Chief of Health Information Management Service or the Clinical Applications Coordinator, as required by VHA and designated by local policy. Managers took action to remove these rules while we were onsite.

Recommendation 8

We recommended that the VISN Director ensure that the System Director requires that managers regularly review CPRS business rules to ensure compliance with VHA regulations and local policy.

The VISN and System Directors agreed with the finding and recommendation. They reported that the Clinical Information System Manager will review CPRS business rules annually and whenever updates, changes, or patches are implemented. This will ensure that all mandated changes are implemented and that business rules are in compliance with VHA and local policies. Managers will complete the annual review by March 31st of each year. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

Review Activities Without Recommendations

Quality Management Program

The purpose of this review was to evaluate whether the system had a comprehensive QM program designed to monitor patient care quality and whether senior managers actively supported the program's activities. We interviewed the system's Director, Chief of Staff, and Coordinator of Performance Improvement (PI). We evaluated policies, PI data, and other relevant documents.

Quality Management. The QM program was effective and well managed. Senior managers supported the program through participation in and evaluation of PI initiatives and through the allocation of resources to the program. Meaningful data were analyzed, trended, and utilized to improve patient care. We made no recommendations.

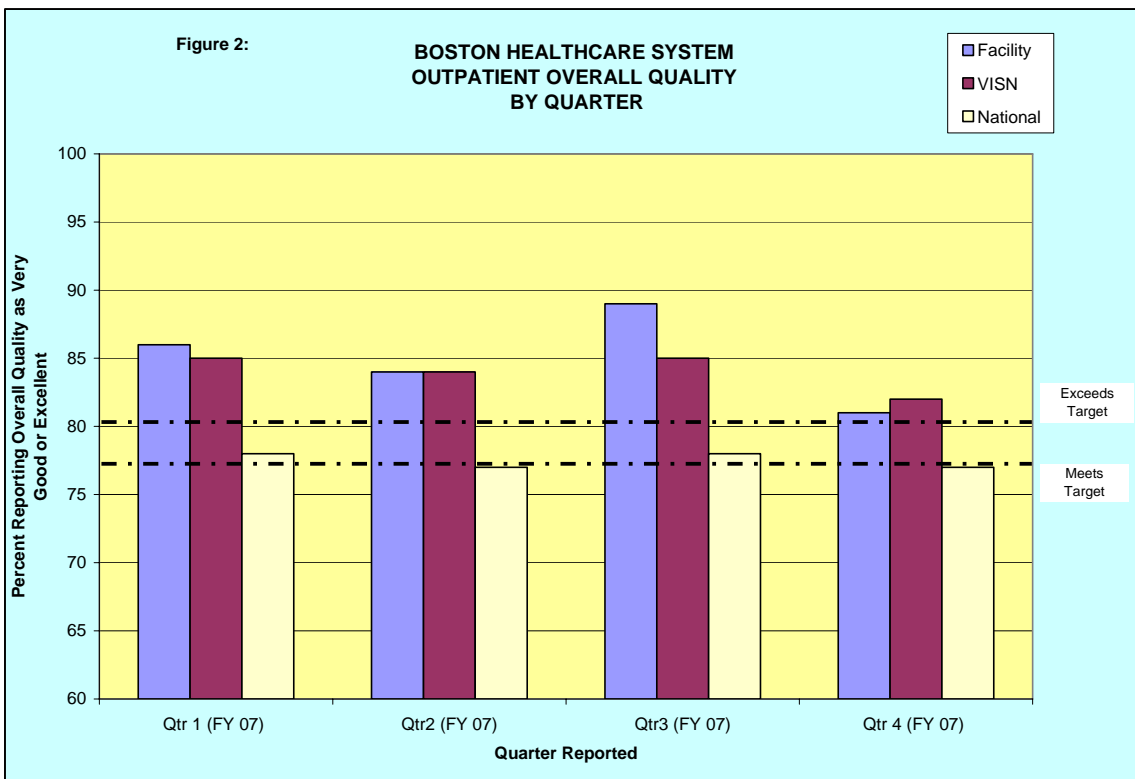
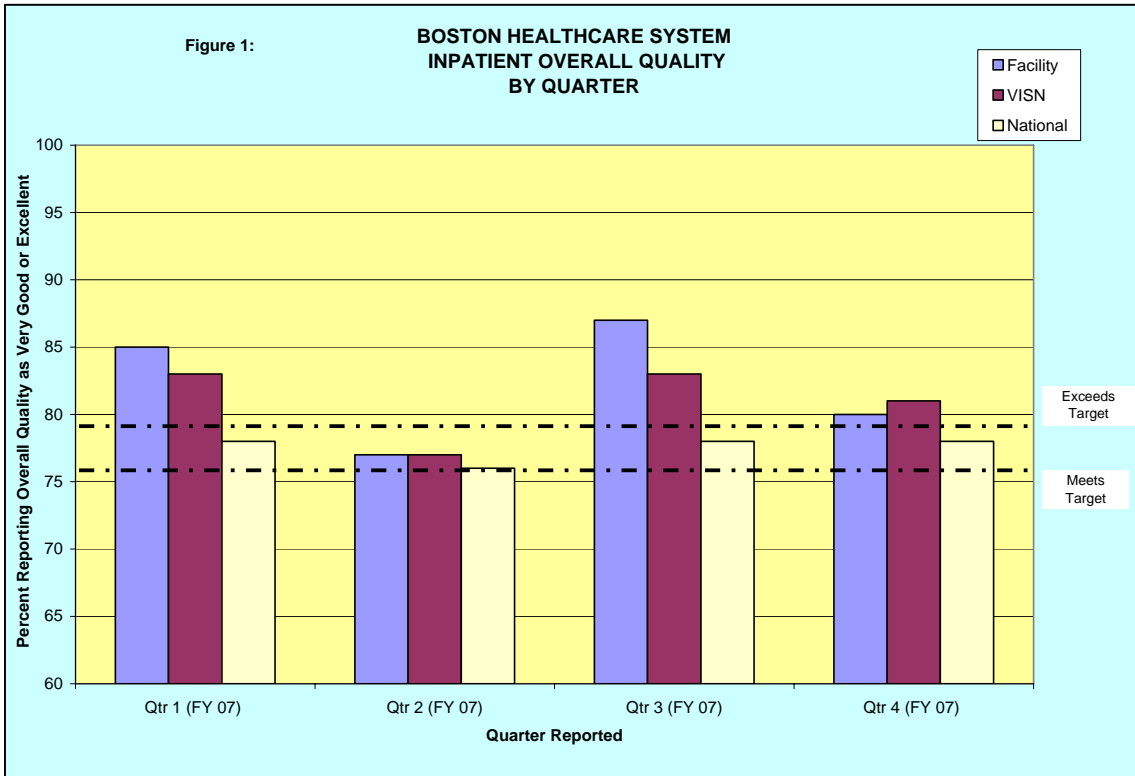
Pressure Ulcer Prevention and Management. As part of the QM review, we followed up on the recommendations regarding pressure ulcer prevention and management documentation from the previous CAP review. In that report, we recommended that a skin care policy be established and implemented and that hospital-acquired pressure ulcer data be accurately collected and thoroughly analyzed.

A facility skin care policy was published and implemented in 2005. An interdisciplinary Skin Care Committee was recently established in accordance with VHA regulations, and we found that data on hospital-acquired pressure ulcers were analyzed and trended. These actions addressed the recommendations from the previous CAP report, and we consider these issues closed.

Survey of Healthcare Experiences of Patients

The purpose of this review was to assess the extent that VHA medical facilities use quarterly or semi-annual SHEP results to improve patient care and services. The Performance Analysis Center for Excellence of the Office of Quality and Performance within VHA is the analytical, methodological, and reporting staff for SHEP. VHA set performance measure goals for patients reporting overall satisfaction of “very good” or “excellent” at 76 percent for inpatients and 77 percent for outpatients.

We reviewed survey results for quarters 1–4 of FY 2007. The system’s scores met or exceeded the target scores for all quarters. Summaries of the findings are displayed in the graphs on the next page.



System managers analyzed their survey results, developed improvement strategies, and monitored the results of the strategies. We found the action plans acceptable. Additionally, in 2007, the system received the Under Secretary for Health's annual customer service award—known as the “STAR” award—for their comprehensive customer service program. We made no recommendations.

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 8, 2008

From: Director, VA New England Healthcare System (10N1)

Subject: Combined Assessment Program Review of the VA Boston Healthcare System, Boston, Massachusetts

To: Director, Bedford Office of Healthcare Inspections (54BN)
Director, Management Review Service (10B5)

Attached please find on pages 14–16 our comments regarding the OIG/CAP review of the VA Boston Healthcare System.

(original signed by:)

TAMMY FOLLENSBEE

Acting Network Director

System Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: April 6, 2008

From: Director, VA Boston Healthcare System (523/00)

Subject: Combined Assessment Program Review of the VA Boston Healthcare System, Boston, Massachusetts

To: Director, Bedford Office of Healthcare Inspections (54BN)
Director, Management Review Service (10B5)

Attached please find on pages 14–16 our comments regarding the OIG/CAP review of the VA Boston Healthcare System.

(original signed by:)

MICHAEL M. LAWSON

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 VISN Director ensure that the System Director appoints CS inspectors in writing and that appointment letters are retrievable for verification purposes.

Concur

VA Boston Healthcare System is in the process of actively recruiting for new controlled substance inspectors and plans to have them in place by June 2008. Each of the new inspectors will be appointed in writing by a memo from the Director. Copies of the appointment memos will be filed with the Controlled Substance Coordinator for verification purposes in the future. Target Completion Date: 6/30/08.

Recommendation 2. We recommended that the VISN Director ensure that the System Director requires that CS inspectors validate two CS transfers from one area to another during monthly inspections.

Concur

CS inspectors utilize a checklist form to guide them through the inspection process. As each task is completed, the inspector initials the form adjacent to the task. The checklist in use at the time of the OIG/CAP review did not provide a line for the inspectors to initial adjacent to the task of "Verifying two transfers." This was corrected while inspectors were still onsite. The new checklists have been distributed for April inspections. Target Completion Date: 4/30/08.

Recommendation 3. We recommended that the VISN Director ensure that the System Director requires that CS inspectors verify that change of shift counts for non-automated dispensing units and weekly inventories of the automated unit are completed during their monthly inspections.

Concur

Both items have been added to the inspector checklist form. The new checklists have been distributed for April inspections. Target Completion Date: 4/30/08.

Recommendation 4. We recommended that the VISN Director ensure that the System Director requires that CS inspectors reconcile 1 day's dispensing from the pharmacy to the automated unit during their monthly inspections.

Concur

This item has been added to the inspector checklist form. The new checklists have been distributed for April inspections. Target Completion Date: 4/30/08.

Recommendation 5. We recommended that the VISN Director ensure that the System Director requires that the CS Coordinator submit quarterly reports summarizing discrepancies, problematic trends, and potential areas for improvement.

Concur

A report summarizing the controlled substance inspection results, identified discrepancies, problematic trends, and potential areas for improvement will be sent to the Director on a quarterly basis. The initial report covering the period of 1/1/08–3/31/08 will be forwarded to the Director by 4/30/08. Copies of these reports will be maintained on file with the Controlled Substance Coordinator for verification purposes in the future. Target Completion Date: 4/30/08.

Recommendation 6. We recommended that the VISN Director ensure that the System Director requires monthly inspections of all portable fire extinguishers, as required by NFPA Code 10 2007.

Concur

VABHS Safety staff will perform a room-by-room inspection to validate and update the current inventory of fire extinguishers. This validated inventory will be used by the contractor for conducting monthly inspections of fire extinguishers. On those days when the contractor is conducting inspections, the safety specialist at that campus will remain on station until the contractor has completed the monthly inspection. The safety specialist will assist the contractor with completing the inspection of any extinguisher in an area that was not accessible to the contractor, or will complete the extinguisher inspection himself/herself by close of business the next day. Safety officer will conduct weekly random checks of fire extinguishers at each campus to verify if the inspections are up to date. Target Completion Date: 4/30/08.

Recommendation 7. We recommended that the VISN Director ensure that the System Director requires that Engineering Service inspect the wander alert system annually and establish a maintenance and repair log.

Concur

Engineering Service will list the wander alert system in the AEMS/MERS equipment inventory and identify the equipment for a yearly preventative maintenance inspection. Engineering Managers at the campuses where the wander alert systems are located will take action to complete the annual inspection of the wander alert system for 2008 and record the completed inspection in the AEMS/MERS database. Target Completion Date: 4/30/08.

Recommendation 8. We recommended that the VISN Director ensure that the System Director requires that managers regularly review CPRS business rules to ensure compliance with VHA regulations and local policy.

Concur

By 4/30/08, the Clinical Information System Manager will conduct a new review of the CPRS business rules. On an annual basis—and whenever updates, changes, or patches are implemented—the CPRS business rules will be reviewed to confirm that all mandated changes have been made and that the business rules are in compliance with VHA and local policy. The annual review will be completed by March 31st of each year. The Clinical Information Systems Manager, in consultation with the Chief, HIMMS, and the Clinical Applications Coordinators, will be responsible for this annual review. Target Completion Date: 4/30/08.

OIG Contact and Staff Acknowledgments

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