Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 08-00529-112

Combined Assessment Program Review of the Ralph H. Johnson VA Medical Center Charleston, South Carolina

April 14, 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 February 11–15, 2008, the OIG conducted a Combined Assessment Program (CAP) review of the Ralph H. Johnson VA Medical Center (the medical center), Charleston, SC. 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 151 medical center employees. The medical center is part of Veterans Integrated Service Network (VISN) 7.

Results of the Review

The CAP review covered five operational areas and activities. We identified the following organizational strength:

- "Paperless" medical records.

We made recommendations in three of the activities reviewed. For these activities, the medical center needed to comply with Veterans Health Administration (VHA) policies and guidance regarding:

- Peer review processes.
- Adverse event disclosure.
- Root cause analysis (RCA) processes.
- Utilization management (UM) activities.
- Medical record reviews.
- Patient satisfaction.
- Electronic medical record (EMR) business rules.

The medical center complied with selected standards in the following two activities:

- Environment of Care (EOC).
- Pharmacy Operations.

This report was prepared under the direction of Victoria Coates, Director, Atlanta Office of Healthcare Inspections, and Carol Torczon, Associate Director, St. Petersburg Office of Healthcare Inspections.

Comments

The VISN and Medical Center Directors agreed with the CAP review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 13–16, for the full text of the Directors' comments.) We will follow up on the proposed actions until they are completed.

(original signed by Dana Moore, PhD,
Deputy Assistant Inspector General for
Healthcare Inspections for:)

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

Introduction

Profile

Organization. The medical center, located in Charleston, SC, is a tertiary care facility that provides a broad range of inpatient and outpatient health care services. Outpatient care is also provided at four community based outpatient clinics in Beaufort, North Charleston, and Myrtle Beach, SC, and in Savannah, GA. The medical center is part of VISN 7 and serves a veteran population of about 40,000 throughout 15 counties in South Carolina and Georgia.

Programs. The medical center provides medical, surgical, mental health, geriatric, and rehabilitation services and is a specialty center for cardiothoracic surgery and cardiac care. It has 117 hospital beds and 28 nursing home beds.

Affiliations and Research. The medical center is affiliated with the Medical University of South Carolina (MUSC) and provides training for 78 medical residents. The medical center also maintains training affiliations with 16 other institutions for nursing, psychology, dietetics, medical technology, and other allied health disciplines. In fiscal year (FY) 2007, the medical center research program had 78 projects—33 funded by VA and 45 funded by other sources—and a budget of $15 million. Important areas of research include cardiology, endocrinology, gerontology, hematology, oncology, rheumatology, nephrology, and mental health.

Resources. In FY 2007, medical care expenditures totaled approximately $201 million. The FY 2008 medical care budget is $232 million. FY 2007 staffing was 1,158 full-time employee equivalents (FTE), including 86 physician and 326 nursing FTE.

Workload. In FY 2007, the medical center treated 41,645 unique patients and provided 23,380 inpatient days in the hospital and 4,468 inpatient days in the Nursing Home Care Unit. The inpatient care workload totaled 3,944 discharges, and the average daily census, including nursing home patients, was 76. Outpatient workload totaled 475,714 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 areas and activities:

- EMR Business Rules.
- EOC.
- Patient Satisfaction.
- Pharmacy Operations.
- QM.

The review covered medical center operations for FY 2007 and FY 2008 through February 12, 2008, and was done in accordance with OIG standard operating procedures for CAP reviews. We also followed up on select recommendations from our prior CAP review of the medical center (*Combined Assessment Program Review of the Ralph H. Johnson VA Medical Center, Charleston, South Carolina,* Report No. 05-00048-84, February 14, 2005). The medical center had corrected all findings related to health care from our prior CAP review.

During this review, we also presented fraud and integrity awareness briefings to 151 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 findings requiring corrective actions.

Organizational Strength

"Paperless" Medical Records

The medical center successfully made the transition from a traditional paper medical record to a fully computerized medical record system within 5 months (December 2006 to April 2007). This accomplishment represents a major culture change within the facility. Medical records department employees transitioned from "file clerks" to their new roles as "scanning clerks," and medical records dating back to the 1960's were archived in accordance with VA policy. This change will improve patient care by providing a single source of current medical information for health care providers.

Results

Review Activities With Recommendations

Quality Management

The purposes of this review were to determine if: (a) the medical center 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 medical center 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 also evaluated documents related to the functioning of the Clinical Executive Board (CEB) and the Performance Improvement Committee (PIC) as well as other relevant QM documents and committee minutes.

The QM program was generally effective in its oversight of the quality of care provided at the medical center, and managers supported QM efforts. Credentialing and

privileging, mortality review, patient complaints, national patient safety goals, resuscitation and outcomes, restraints and seclusion, and system redesign/patient flow were monitored effectively. However, we identified the following program areas that needed strengthening:

Peer Review. The 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 within 45 days by a peer of the same discipline with subsequent Peer Review Committee (PRC) evaluation and concurrence with the findings within 120 days. We evaluated peer review activities conducted for FY 2007 and for FY 2008 through February 12, 2008, and identified the following issues:

- The peer review database identified 34 completed peer review cases. We found that 18 initial peer reviews (53 percent) were not completed within the 45-day timeframe and that 16 peer reviews (47 percent) were not reviewed by the PRC within the 120-day timeframe.
- PRC minutes did not clearly reflect rationales for peer review level changes.
- Trending and analysis of data were not regularly presented to the CEB or PIC.

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 and data evaluation should be conducted in accordance with policy to ensure that providers perform according to accepted community standards and that improvement actions are taken when indicated.

Adverse Event Disclosure. The medical center did not comply with all elements of VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, issued October 27, 2005. The medical center process to evaluate events that could potentially require institutional disclosure needed enhancement. Institutional disclosure is a formal process that is completed when serious injury, death, or potential legal liability are involved. During FY 2007, the medical center completed an appropriate institutional disclosure for one case. However, during our review, we

identified five additional cases that should have been evaluated for possible institutional disclosure. QM staff told us that some events had been discussed, but they could not provide documentation that appropriate evaluations were completed. Without a defined process for adequate evaluation of events that potentially require disclosure, managers could not be assured that patients were provided with information needed to make decisions.

Root Cause Analyses. We found that the timeliness of RCA completion 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 that RCAs be conducted within 45 days of the medical center's identification of need. Of the 13 RCAs conducted during FY 2007 and FY 2008 through January 24, 2008, we found that 7 were not completed within the 45-day requirement. Without timely completion of the RCA process, managers could not be assured that improvement actions were promptly initiated.

Utilization Management. The medical center's UM process, including collection, reporting, and referral of UM data, did not comply with VHA Directive 2005-009, *Utilization Management*, issued March 7, 2005. While appropriate UM elements were in place at the time of our review, data collection didn't begin until FY 2007, and data reporting didn't begin until FY 2008. We also found that cases not meeting the standardized criteria were not being referred to a physician reviewer. Without referral of UM data to the physician reviewer, managers could not be assured that resources were properly utilized, trends were identified, and actions were initiated.

Medical Staff Review Activities. The medical staff review activities did not include all elements required by The Joint Commission (JC). The JC requires that the medical staff monitor blood and blood products usage and operative and other invasive procedures for performance improvement. The medical center has defined committees responsible for monitoring these review processes. We found that committee minutes did not reflect consistent collection and analysis of data and that staff did not compare data with internal or external benchmarks. In addition, the Operative and Other Invasive Procedure Committee minutes did not

reflect documented reviews of major discrepancies between pre- and post-operative diagnoses and did not contain critical analysis of data, including National Surgical Quality Improvement Program data. Without appropriate monitoring and evaluation of these medical staff review activities, managers could not be assured that performance improvement activities were initiated when indicated.

Medical Record Review. We found that the medical record reviews conducted by Health Information Management Service (HIMS) staff did not include all components of review required by VHA. The EMR system allows copying and pasting of text, but VHA policy states that this should be used with caution. We found that the medical center did not comply with the requirement in VHA Handbook 1907.01, *Health Information Management and Health Records,* issued August 25, 2006, to monitor copying and pasting as part of the ongoing medical record review process. Routine copying and pasting of text can result in confusing and misleading medical information that could negatively impact patient care. Without adequate medical record reviews, managers could not be assured that electronic documentation functions were being appropriately used at the medical center.

Recommendation 1 We recommended that the VISN Director ensure that the Medical Center Director requires timely completion of peer reviews, documentation of rationales for peer review level changes, and presentation of trending and analysis data to the CEB or PIC.

The VISN and Medical Center Directors agreed with the findings and recommendation and reported that PRC processes have been reviewed and that plans for improvement have been initiated. We will follow up on the planned actions until they are completed.

Recommendation 2 We recommended that the VISN Director ensure that the Medical Center Director requires that clear processes are in place to adequately evaluate events that could potentially require disclosure.

The VISN and Medical Center Directors agreed with the finding and recommendation and reported that evaluation of cases for disclosure will be documented in the PRC minutes and in the RCA summary, if applicable. We will follow up on the planned actions until they are completed.

Recommendation 3 We recommended that the VISN Director ensure that the Medical Center Director requires timely completion of RCAs.

The VISN and Medical Center Directors agreed with the finding and recommendation and reported that patient safety processes have been reviewed and that plans for improvement have been initiated. We will follow up on the planned actions until they are completed.

Recommendation 4 We recommended that the VISN Director ensure that the Medical Center Director requires that UM processes comply with VHA policy.

The VISN and Medical Center Directors agreed with the finding and recommendation and reported that the medical center's UM policy has been updated and that processes have been implemented in accordance with VHA policy. We will follow up on the planned actions until they are completed.

Recommendation 5 We recommended that the VISN Director ensure that the Medical Center Director requires that copying and pasting of notes be included in HIMS medical record reviews in accordance with VHA policy.

The VISN and Medical Center Directors agreed with the finding and recommendation and reported that the Medical Records Review Committee will include copying and pasting of notes in HIMS medical record reviews. We will follow up on the planned actions until they are completed.

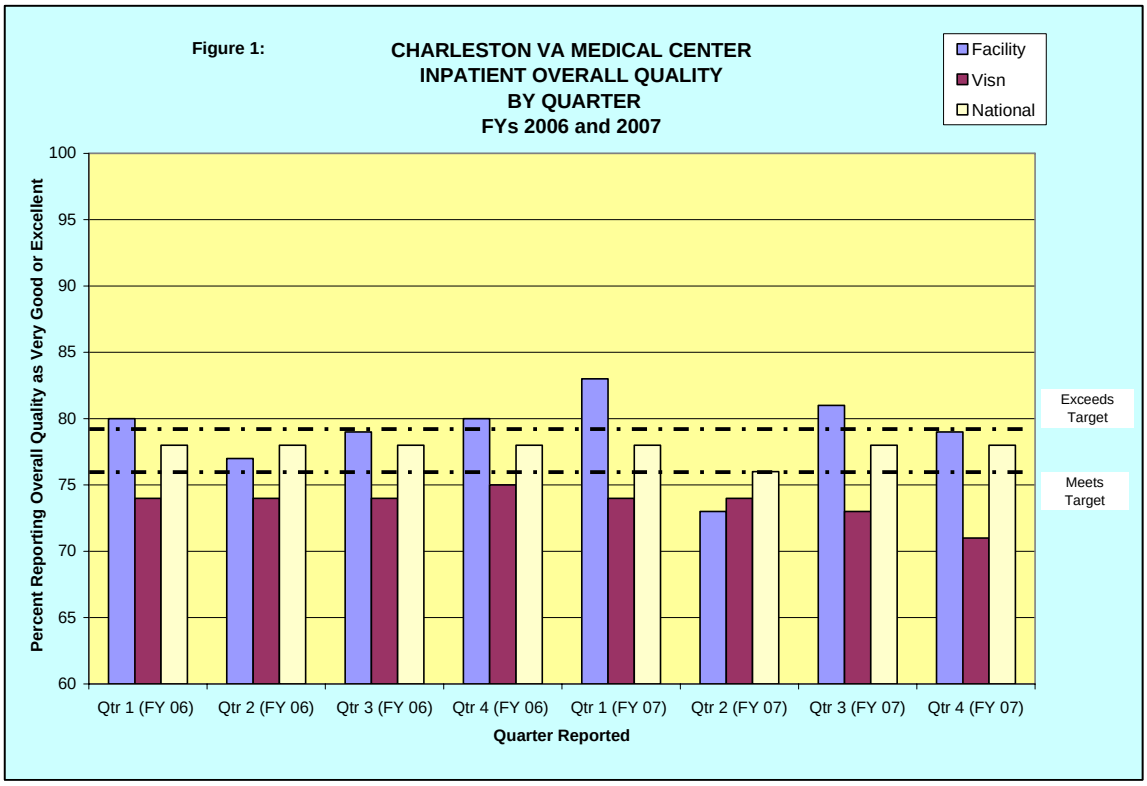
Patient Satisfaction

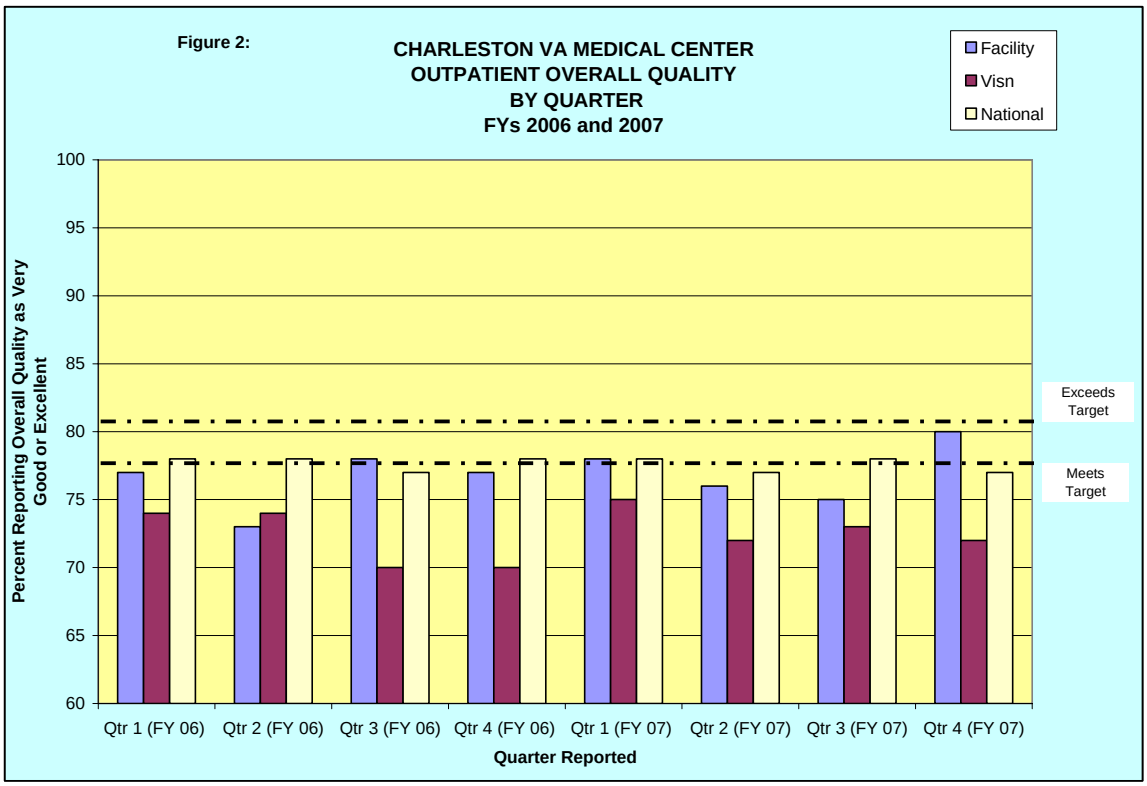
The Survey of Healthcare Experiences of Patients (SHEP) is aimed at capturing patient perceptions of care in 12 service areas, including access to care, coordination of care, and courtesy. VHA relies on the Office of Quality and Performance's analysis of the survey data to make decisions to improve the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

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

The graphs below and on the next page show the medical center's performance in relation to national and VISN performance for FYs 2006 and 2007. Figure 1 shows the medical center's SHEP performance measure (PM) results for inpatients, and Figure 2 shows the medical center's SHEP PM results for outpatients.

The medical center met or exceeded the established target for inpatient overall quality for 7 of the last 8 quarters. The established target was met for only 3 of the last 8 quarters for outpatient overall quality. The medical center has identified opportunities for improvement with a focus on outpatient care but has not implemented an action plan that has measurable, achievable goals or that identifies who is responsible for implementation of the improvement plan elements.





Recommendation 6

We recommended that the VISN Director ensure that the Medical Center Director requires implementation of an action plan to improve patient satisfaction that includes measurable goals and assigns responsibility for completion of tasks.

The VISN and Medical Center Directors agreed with the finding and recommendation. A customer service plan was developed and reviewed by the OIG during the CAP visit. The plan, which includes specific responsibilities and actions, was approved by leadership on March 14, 2008. We found the customer service plan to be acceptable, and we will follow up on the proposed actions until they are completed.

Electronic Medical Record Business Rules

Business rules define which groups or individuals are allowed to edit or delete documentation in EMRs. The health record, as defined in VHA Handbook 1907.01, 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 guidance to all medical centers 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 guidance sent in October 2004.

During our review, we found that the medical center had eight business rules that needed to be removed to limit retraction, amendment, or deletion of notes to the Privacy Officer, the Chief of HIMS, or their designees. Medical center staff took action to remove these business rules while we were onsite.

Recommendation 7 We recommended that the VISN Director ensure that the Medical Center Director requires continued compliance with VHA Handbook 1907.01 and the October 2004 OI guidance related to EMRs.

The VISN and Medical Center Directors agreed with the finding and recommendation. The Chief Information Officer will work with the medical center Office of Information and Technology staff to ensure that compliance is maintained. Business rules will be reviewed quarterly, and actions will be taken as necessary. The corrective actions are acceptable, and we consider this recommendation closed.

Review Activities Without Recommendations

Environment of Care

The purpose of this review was to determine if the medical center maintained a comprehensive EOC program that complied with National Center for Patient Safety, Occupational Safety and Health Administration, and JC standards.

We inspected clinical and non-clinical areas throughout the medical center to evaluate cleanliness, safety, and infection control (IC). The clinical areas we inspected included medical, surgical, and mental health units and medical and surgical intensive care areas. We also inspected outpatient clinics, all diagnostic testing areas, and many public areas. Managers generally maintained a safe and clean health care environment. The IC program monitored, trended, analyzed, and reported data to clinicians, the IC Committee, and the

EOC Committee for implementation of quality improvements. We made no recommendations.

Pharmacy Operations

The purpose of this review was to evaluate whether VA health care facilities had adequate controls to ensure the security and management of controlled substances and to ensure the safety and security of the inpatient and outpatient pharmacies' internal physical environments. We also assessed whether clinical managers had processes in place to monitor patients for polypharmacy.

We assessed whether the medical center's policies and practices were consistent with VHA regulations governing pharmacy and controlled substances security. We inspected inpatient and outpatient pharmacies for security, EOC, and IC concerns. We interviewed appropriate Pharmacy Service and Police and Security Service personnel, as necessary.

Pharmacy Controls. Our review showed that the medical center had appropriate policies and procedures to ensure security of controlled substances and to ensure the safety and security of the pharmacies' physical environments. Prior to May 2007, controlled substances inspections were not always conducted in accordance with VHA regulations, and there was inconsistent follow-up for resolution of controlled substances count discrepancies during the period September 2006–May 2007.

The medical center appointed a Controlled Substances Coordinator (CSC) in May 2007. The CSC implemented necessary corrective actions, and training records showed that the CSC and controlled substances inspectors received appropriate training to execute their duties. Any discrepancies found since May 2007 have been followed up in accordance with VHA policy. We also found that managers reported all controlled substances diversions or suspected diversions to the OIG. The pharmacies were secure, clean, and well maintained.

Polypharmacy. Pharmacological regimens involving multiple medications are often necessary to prevent or control disease states; however, excessive use of medications can result in adverse reactions and increased risk 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.

Our review showed that managers had developed initial processes and monitors to assist clinical pharmacists to identify patients who were prescribed multiple medications. We made no recommendations.

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: March 27, 2008

From: Director, VA Southeast Network (10N7)

Subject: **Combined Assessment Program Review of the Ralph H. Johnson VA Medical Center, Charleston, South Carolina**

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

Director, Management Review Service (10B5)

I have reviewed the draft report of the Inspector General's Combined Assessment Program (CAP) of the Ralph H. Johnson VA Medical Center. We concur with the findings and recommendations.

(original signed by :)

Mark Anderson for Lawrence A. Biro

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: March 24, 2008

From: Director, Ralph H. Johnson VA Medical Center (534/00)

Subject: **Combined Assessment Program Review of the Ralph H. Johnson VA Medical Center, Charleston, South Carolina**

To: Director, VA Southeast Network (10N7)

1. I have reviewed the draft report of the Inspector General's Combined Assessment Program (CAP) of the Ralph H. Johnson VA Medical Center. We concur with the findings and recommendations.

2. I appreciate the opportunity for this review as a continuing process to improve the care to our veterans.

(original signed by:)

JOHN E. BARILICH, MSW, MBA

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 Medical Center Director requires timely completion of peer reviews, documentation of rationales for peer review level changes, and presentation of trending and analysis data to the CEB or PIC.

Concur

The Peer Review Committee processes have been reviewed, and plans for improvement have been initiated.

Recommendation 2. We recommended that the VISN Director ensure that the Medical Center Director requires that clear processes are in place to adequately evaluate events that could potentially require disclosure.

Concur

Evaluation of cases for Disclosure will be documented in the Peer Review Committee minutes and Root Cause Analyses summary, if applicable.

Recommendation 3. We recommended that the VISN Director ensure that the Medical Center Director requires timely completion of RCAs.

Concur

Patient Safety processes have been reviewed, and plans for improvement have been initiated.

Recommendation 4. We recommended that the VISN Director ensure that the Medical Center Director requires that UM processes comply with VHA policy.

Concur

The facility policy has been updated, and processes have been implemented in accordance with the VHA Directive.

Recommendation 5. We recommended that the VISN Director ensure that the Medical Center Director requires that copying and pasting of notes be included in HIMS medical record reviews in accordance with VHA policy.

Concur

The Medical Records Review Committee will include copying and pasting of notes in the HIMS medical record reviews.

Recommendation 6. We recommended that the VISN Director ensure that the Medical Center Director requires implementation of an action plan to improve patient satisfaction that includes measurable goals and assigns responsibility for completion of tasks.

Concur

A Customer Service plan was developed and reviewed by the OIG during the CAP visit. The plan, which includes specific responsibilities and actions, was approved by leadership on March 14, 2008.

Recommendation 7. We recommended that the VISN Director ensure that the Medical Center Director requires continued compliance with VHA Handbook 1907.01 and the October 2004 OI guidance related to EMRs.

Concur

The CIO will work with the facility OI&T staff to ensure compliance is maintained. Business rules will be reviewed quarterly and actions taken as necessary.

OIG Contact and Staff Acknowledgments

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