Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 07-00167-22

Combined Assessment Program Review of the VA Nebraska Western Iowa Health Care System Omaha, Nebraska

November 13, 2007

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 August 6–10, 2007, the OIG conducted a Combined Assessment Program (CAP) review of the VA Nebraska Western Iowa Health Care System (the system), Omaha, NE. 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 61 system employees. The system is part of Veterans Integrated Service Network (VISN) 23.

Results of the Review

The CAP review covered seven operational activities. We identified the following organizational strength and reported accomplishment:

- Performance Improvement (PI) as a Leadership Activity.

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

- Eliminate duplicate medical records and maintain one complete, secured medical record.
- Complete peer reviews within 120 days.
- Monitor blood and blood product use on a concurrent basis.
- Ensure all scopes of practice for research personnel are reviewed and approved by the Associate Chief of Staff for Research and Development (ACOS/R&D).

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

- Business Rules.
- Community Based Outpatient Clinic (CBOC).
- Surgical Care Improvement Project (SCIP).
- Survey of Healthcare Experiences of Patients (SHEP).

This report was prepared under the direction of Virginia L. Solana, Director, and Jennifer Kubiak, Healthcare Inspector, Kansas City Office of Healthcare Inspections.

Comments

The VISN and System Directors agreed with the CAP review findings and recommendations. (See Appendixes A and B, pages 14–18, 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 consists of two facilities located in Grand Island and Omaha, NE, that provide a broad range of inpatient, outpatient, rehabilitative, and long-term health care services. Outpatient care is also provided at three CBOCs in Lincoln, Norfolk, and North Platte, NE. The system is part of VISN 23 and serves a veteran population of about 172,500 in 104 counties in Nebraska, western Iowa, and portions of Kansas and Missouri.

Programs. The system provides medical, surgical, behavioral health, dental, geriatric, rehabilitation, and long-term care services. The system has 126 hospital beds at the Omaha facility and 76 nursing home beds at the Grand Island facility.

Affiliations and Research. The system is affiliated with the University of Nebraska and with Creighton University and provides training for 460 residents, as well as other disciplines, including nursing, dental, pharmacy, social work, dietetics, physician assistant, and occupational therapy. In fiscal year (FY) 2006, the system research program had 181 active projects and a budget of $7.9 million. Important areas of research included diabetes, liver and pulmonary disease, cancer, and alcohol-related diseases.

Resources. In FY 2006, medical care expenditures totaled $244.6 million. The FY 2007 medical care budget was $256.8 million. FY 2006 staffing was 1,344 full-time employee equivalents (FTE), including 75 physician and 261 nursing FTE.

Workload. In FY 2006, the system treated 47,398 unique patients and provided 23,337 inpatient days in the hospital and 25,660 inpatient days in the Nursing Home Care Unit. The inpatient care workload totaled 4,675 discharges, and the average daily census, including nursing home patients, was 134. Outpatient workload totaled 408,358 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 system 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, employees, and patients; and reviewed clinical and administrative records. The review covered the following seven activities:

- Business Rules.
- CBOC.
- Environment of Care (EOC).
- QM.
- SCIP.
- SHEP.
- Unlicensed Physicians in Research.

The review covered system operations for FY 2006 and FY 2007 through July 31, 2007, 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 system (*Combined Assessment Program Review of the VA Nebraska Western Iowa Health Care System, Omaha, Nebraska,* Report No. 04-02398-70, January 18, 2005). The system had corrected all health care related conditions identified during our prior CAP review.

During this review, we also presented fraud and integrity awareness briefings for 61 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 Strengths

Performance Improvement as a Leadership Activity

In FY 2006, the system developed a program where every supervisor would lead or fully participate in a PI project as one requirement for an outstanding performance rating. The Quality Manager scheduled meetings with individual supervisors to provide guidance on how to involve employees in identifying possible improvements, utilize data to support choices for improvements, establish objectives, form and develop teams, define measurements, develop methods to celebrate success, trend data, and use graphics to demonstrate the improvements. Over 100 meetings were held the first year.

These coaching sessions were geared toward a goal of moving the supervisors into a firm leadership role. By the end of the year, 96 percent of the supervisors were completing plans for data-driven PI projects. QM scheduled supervisors to report the outcomes of their projects to the PI Council. QM required that the reports include graphic display of trended data. This requirement facilitated supervisors' education regarding display tools and techniques. Supervisors have now embraced the concept and practice of PI as part of their daily work within their respective departments and are able to use data more effectively.

Results

Review Activities With Recommendations

Environment of Care

The purpose of this review was to determine whether the system complied with selected infection control (IC) standards and maintained a clean and safe patient care environment. The system is required to establish a comprehensive EOC program that fully meets National

Center for Patient Safety, Occupational Safety and Health Administration, and Joint Commission standards.[1]

We evaluated the IC program to determine compliance with Veterans Health Administration (VHA) directives that require management to collect and analyze data to improve performance. IC staff appropriately collected, trended, and analyzed data related to infections and involved clinicians in improvement initiatives to reduce infection risks for patients and staff.

We also reviewed the system's approval for use, inventory, handling, storage, and disposal of tritium. Tritium is a radioactive material that has a long period of radioactivity and is used in research protocols. We determined that the system had current processes in place that complied with Nuclear Regulatory Commission and VHA requirements.

We inspected inpatient and outpatient care areas, including long-term care and rehabilitation. We inspected occupied and unoccupied patient rooms, procedure areas, bathrooms, supply rooms, and medication areas. Safety standards were met, and we found the system to be generally clean and well maintained.

While inspecting an outpatient procedure area, we found an unsecured office with hundreds of paper file folders containing patient health information. Staff reported that they stored the records there permanently to ensure immediate availability for physician review. The folders contained old paper medical records and paper copies of current electronic medical record notes.

For continuity of care, The Joint Commission requires hospitals to maintain a complete medical record that is accessible to providers of care, as well as to staff from financial and business offices, PI, and research. The intent of this standard is to reduce the risks associated with duplicate, incomplete, and inaccessible medical records. VHA has implemented an electronic medical record, the Computerized Patient Record System (CPRS), to meet this requirement. VHA requires that a medical record professional be in charge of all records to ensure completeness, accessibility, and security of information. The

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

medical records that staff maintained in this outpatient procedure area did not meet the requirements, and patient information was not secure.

Recommendation 1 We recommended that the VISN Director ensure that the System Director requires staff to eliminate the duplicate record system and maintain one complete, secured medical record.

The VISN and System Directors concurred with our findings and recommendation. System managers have transferred all patient records from the Gastroenterology Laboratory to the medical records file room. Records will be maintained in the file room, and there is a formal request process to remove records to other areas. We find this action plan appropriate and consider this recommendation closed.

Quality Management

The purpose of this review was to evaluate whether the system's QM program provided comprehensive oversight of the quality of care and whether senior managers supported the program's activities. We interviewed the system's Director, Chief of Staff, Chief Nurse Executive, and Quality Manager. We evaluated plans, policies, and other relevant documents.

The QM program was generally effective in providing oversight of the system's quality of care. Appropriate review structures were in place for 12 of the 14 program activities reviewed. However, we identified two areas that needed improvement.

Peer Review. VHA guidelines specify national program requirements for the peer review process. Once the need for peer review is determined, VHA policy requires that peer reviews be completed within 120 days. Of the 70 completed peer reviews that we evaluated, clinicians only completed 51 percent within the required timeframe.

Blood Use. The Joint Commission and VHA require that the system regularly collect data that measure the potentially high-risk processes of blood and blood product use. The system policy required monthly reviews, but reviews had not been performed since December 2006. The Quality Manager stated that the person responsible for the blood use reviews left the position and that no one had taken over the responsibility. While we were onsite, QM staff were

developing a process to concurrently review blood use and to catch up on the backlog.

Recommendation 2 We recommended that the VISN Director ensure that the System Director requires that clinicians complete peer reviews within 120 days.

The VISN and System Directors concurred with our findings and recommendation. System managers have developed plans for tracking peer review cases in order to complete these reviews within 120 days. Responsibilities for tracking and communicating status are designated within these plans. We find this action plan appropriate and will follow up on reported implementation actions to ensure completion.

Recommendation 3 We recommended that the VISN Director ensure that the System Director requires concurrent review of blood and blood product use.

The VISN and System Directors concurred with our findings and recommendation. System managers have completed preliminary blood transfusion reviews through July 2007. Final reviews are pending for the months of April and July 2007. These reviews are to be completed by November 30, 2007. We find this action plan appropriate and will follow up on reported implementation actions to ensure completion.

Unlicensed Physicians in Research

The purpose of this review was to determine whether research activities performed by unlicensed physicians constitute the practice of medicine.

In order to practice medicine in the United States, a graduate of medical school, with few exceptions, must complete a United States residency. This requirement exists regardless of the skills, training, or experience of the graduates. Medical school graduates who cannot or do not complete an internship or residency in the United States and do not otherwise have an exemption, are not eligible for licensure. If engaged in research activities, these individuals may function in roles such as study coordinators or research assistants, but they cannot practice medicine. Activities traditionally considered to constitute the practice of medicine include performing invasive procedures, conducting physical examinations, and altering medications.

VHA Handbook 1200.5, *Requirements for the Protection of Human Subjects in Research*, issued July 15, 2003, requires the system Director to ensure that Institutional Review Board members and investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations. As a result, unlicensed physicians operate under a scope of practice. "Scope of practice" is a term used to describe activities that may be performed by health care workers, regardless of whether they are licensed independent health care providers.

The system identified one unlicensed physician assigned to one human subjects research study as a research team member. We reviewed seven medical records of patients enrolled in that research study. Of the seven medical records we reviewed, we did not find any progress notes by the unlicensed physician or any other documentation of activities that he performed. The ACOS/R&D stated that this unlicensed physician was hired to perform data management activities after the clinical research was completed.

Upon review of the unlicensed physician's scope of practice, we found that it had not been reviewed and approved by the ACOS/R&D. This is a violation of the 2003 guidance on verifying the credentialing of all individuals involved in human subjects research that is posted on the Office of Research and Development's website.

Recommendation 4 We recommended that the VISN Director ensure that the System Director requires that the ACOS/R&D review and approve all scopes of practice for system personnel engaged in research activities.

The VISN and System Directors concurred with our findings and recommendation. System managers have implemented a process to ensure that all scopes of practice for personnel engaged in research are reviewed and approved by the ACOS/R&D. We find this action plan appropriate and consider this recommendation closed.

Review Activities Without Recommendations

Business Rules

The purpose of this review was to determine whether business rules governing CPRS comply with VHA policy. CPRS business rules define what functions certain groups or individuals are allowed to perform in the health record.

The health record, as defined in VHA Handbook 1907.01, *Health Information Management and Health Records*, issued August 25, 2006, includes the combined electronic and paper medical record and is also known as the legal health record. It includes items, such as physician orders, chart notes, examinations, and test reports. Once notes are signed, they must be kept in unaltered form. New information, corrections, or different interpretations may be added as further entries to the record, as addenda to the original notes, or as new notes—all accurately reflecting the times and dates recorded.

On October 20, 2004, VHA's Office of Information (OI) provided guidance that advised VHA facility managers to review their business rules and delete any rules that allowed editing of signed medical records. Following this guidance, OI has recommended that any editing of signed records be limited to the facility's Privacy Officer. On June 7, 2006, VHA issued a memorandum to all VISN Directors instructing all VA medical centers to comply with the informational patch sent in October 2004.

We reviewed VHA and system information and technology policies and interviewed the CPRS trainer and the Chief of Information Technology (IT) Service. We found that IT staff had reviewed local business rules to assess compliance with VHA policy and had updated or deleted rules that were not applicable. As a result, all of the business rules the system provided for our review complied with VHA requirements. We made no recommendations.

Community Based Outpatient Clinic

The purpose of this review was to assess the effectiveness of CBOC operations and to determine whether CBOCs comply with selected standards of operation. A CBOC is a VA-operated, VA-funded, or VA-reimbursed health care facility or site geographically distinct or separate from a parent medical facility. VHA expanded ambulatory and primary care areas under Federal legislation passed in 1996, which included the creation of CBOCs throughout the United States. The enactment of this legislation requires that VA maintain its capacity to provide for the specialized treatment and rehabilitation needs of disabled veterans within distinct programs or facilities that are dedicated to the specialized needs of those veterans in a manner that affords them reasonable access to care and services. We reviewed compliance with VHA regulations regarding selected

standards of operation, services, patient safety, provision of emergency care, and credentialing and privileging.

We visited the CBOC located in Lincoln, NE, that treated 11,486 veterans in FY 2006. We interviewed primary care employees and reviewed documents related to the CBOC's services. Specifically, we reviewed the management of patients taking warfarin (an anticoagulant medication) to determine if the same standards of care provided to patients at the parent facility in Omaha were in effect at the CBOC. We determined that the same standards applied because clinical pharmacists managed all CBOC patients who were taking warfarin in an anticoagulation clinic. CBOC clinical pharmacists maintain the same standards of care and expectations as clinical pharmacists who treat patients in the anticoagulation clinic at the parent facility. All patients attend an initial education class as part of their first anticoagulation clinic visit. If patients need to begin medication prior to that clinic visit, primary care physicians manage their care. The CBOC is in the process of installing a toll-free help line number specifically for the anticoagulation clinic.

We interviewed five veterans who were being treated at the CBOC the day of our inspection. The veterans we interviewed reported a high level of satisfaction with their providers and the care they receive. They are grateful for the convenient location of the clinic.

We evaluated the clinic's EOC and determined that the clinic was clean and safe and had current emergency preparedness plans in place. CBOC staff had received emergency training and were aware of their roles during emergencies. The automated external defibrillator was in working order, and maintenance documentation was current.

We also reviewed credentialing and privileging files, education records, and background investigations for six randomly selected CBOC staff. The files of three CBOC providers and three CBOC nurses showed documentation of current licensure, credentials, mandatory education, and completed background checks.

We found that the CBOC complied with all regulations and standards. We made no recommendations.

Surgical Care Improvement Project

The purpose of this 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. In 2005, VHA adopted surgical infection performance measures (PMs) from the Centers for Medicare and Medicaid Services and The Joint Commission into its performance measurement system to improve surgical patient outcomes.

We evaluated the following VHA PMs for FY 2006 and the 3rd quarter of FY 2007:

- Timely administration of prophylactic 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. The time of administration depends on the antibiotics given. The VHA target was 90 percent.
- 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. The time depends on the surgical procedure performed. The VHA target was 87 percent.
- 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 post-operative. Decreased core body temperature is associated with impaired wound healing. The VHA target was 70 percent.

We reviewed system PMs and compared them to VHA established targets. For timely post-operative discontinuation of prophylactic antibiotics, the system scored 53 percent for the 4th quarter of FY 2006. We interviewed key staff to determine whether clinical managers had developed and implemented action plans for that PM since it fell below the VHA established target of 87 percent.

The system implemented post-operative order sets limiting doses of prophylactic antibiotics to two doses, which requires that clinicians write a new order if they want to continue

antibiotics beyond the established timeframe. The system provided education to resident and staff physicians on the clinical evidence that supports discontinuing the antibiotic within the designated timeframe. The system also participated in the VISN 23 Surgical Site Infection Collaborative, with a goal of reducing surgical infection rates through evidence-based medical practice and standardized patient care. As a result of these initiatives, PM scores are now at 93 percent.

We reviewed the medical records of 22 patients who had surgery performed during the 3rd quarter of FY 2007. The review included medical records for each of the following surgical categories: (a) colorectal, (b) vascular, (c) orthopedic (knee or hip replacement), and (d) hysterectomy. The system did not have any cases of cardiac surgery. Review results are displayed in the following table:

Antibiotic administered timely	Antibiotic discontinued timely	Body temperature control (colorectal surgery)
95 percent (21/22)	100 percent (22/22)	100 percent (4/4)

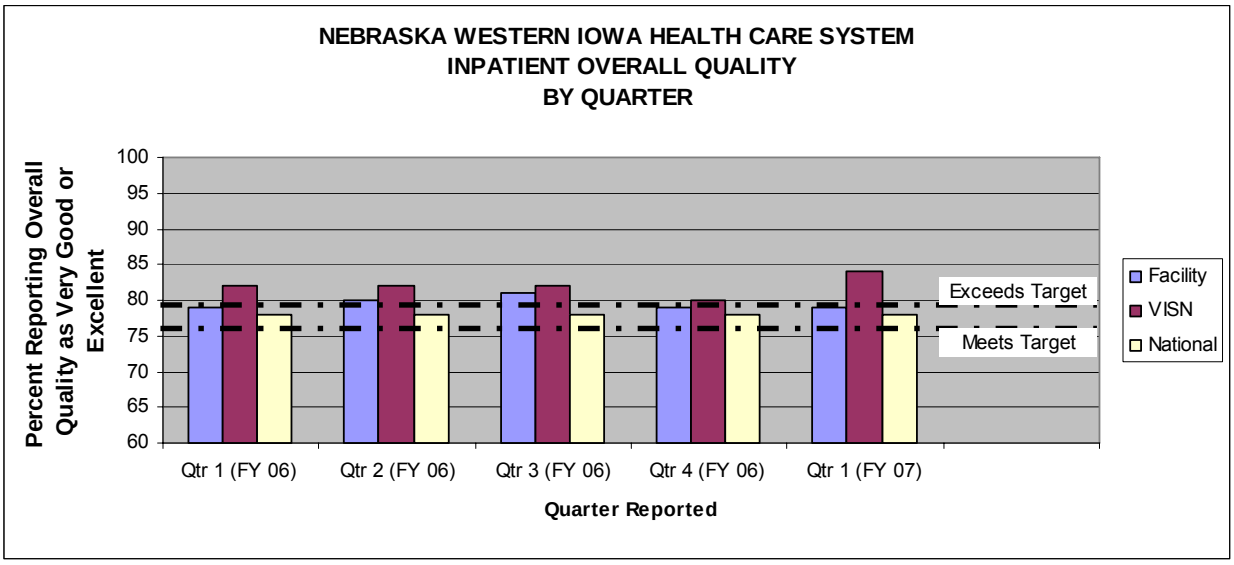
Our medical record review supported the improved PM scores, demonstrating that the system appropriately administered and discontinued antibiotics or documented clinical exceptions. Clinicians monitored and controlled immediate post-operative body temperature for patients who had colorectal surgery.

Because we determined that the system had initiated appropriate corrective actions to improve care, we made no recommendations.

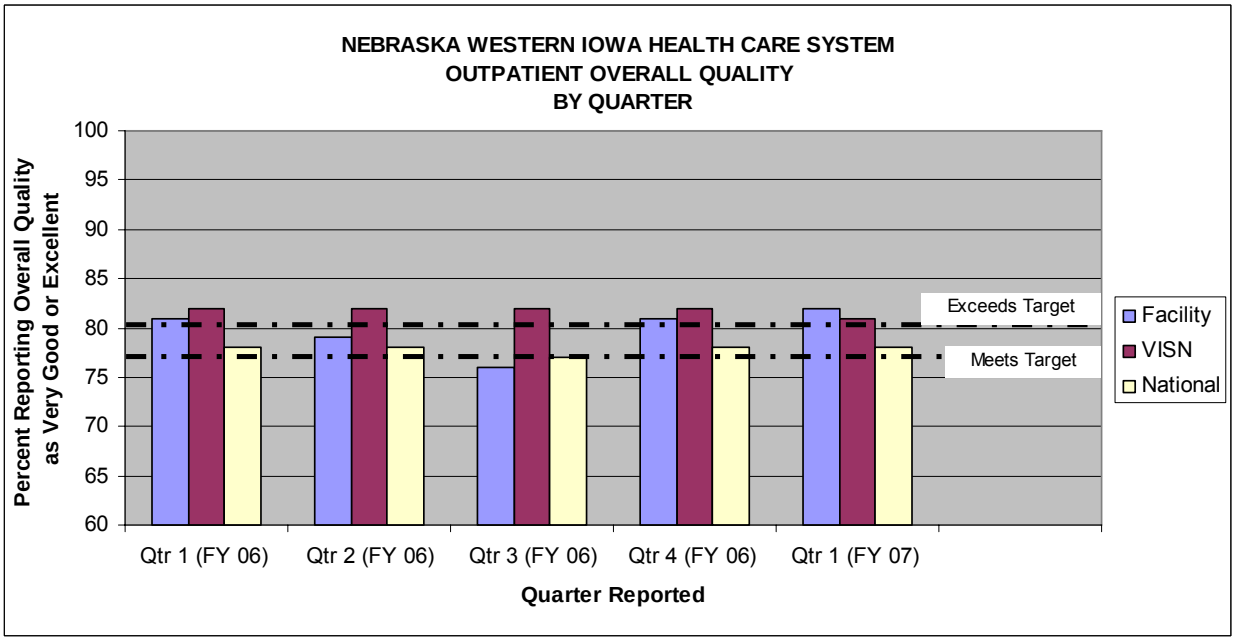
Survey of Healthcare Experiences of Patients

The purpose of this review was to assess the extent that VHA medical centers use the quarterly/semi-annual survey report results of patients' health care experiences with the VHA system to improve patient care, treatment, 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 PM results for patients reporting overall satisfaction of "very good" or "excellent" at 76 percent for inpatients and 77 percent for outpatients.

The chart below shows the system's SHEP PM results for inpatients.



The chart below shows the system's SHEP PM results for outpatients.



The system exceeded the established target for all 4 quarters of FY 2006 for inpatient results and for 3 of 4 quarters of FY 2006 for outpatient results. The system identified opportunities for improvement based on the SHEP

scores and developed an action plan targeting specific services and departments. The system has implemented the action plan, and there is evidence of ongoing activities and of evaluation of the plan for effectiveness. We made no recommendations.

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 1, 2007

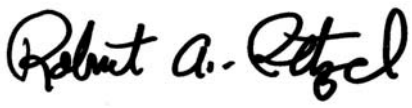
From: Director, Midwest Health Care Network (10N23)

Subject: **Combined Assessment Program Review of the VA Nebraska Western Iowa Health Care System, Omaha, Nebraska**

To: Director, Kansas City Regional Office of Healthcare Inspections (54KC)

Director, Management Review Office (10B5)

Concur with recommendations and actions planned.



ROBERT A. PETZEL, M.D.

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: October 3, 2007

From: Director, VA Nebraska Western Iowa Health Care System (636/00)

Subject: **Combined Assessment Program Review of the VA Nebraska Western Iowa Health Care System, Omaha, Nebraska**

To: **Director, Kansas City Regional Office of Healthcare Inspections (54KC)**

1. I concur with the recommendations and actions planned and taken.

2. If you have any questions, please telephone me at (402) 449-0600.

AL WASHKO

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 requires staff to eliminate the duplicate record system and maintain one complete, secured medical record.

Concur

Response: We have transferred all patient records from the Gastroenterology Laboratory to the Medical Records File Room and will request the paper chart when needed. No paper patient records are now filed in the Gastroenterology Laboratory at Nebraska-Western Iowa Health Care System. **Action completed on October 1, 2007.**

Recommendation 2. We recommended that the VISN Director ensure that the System Director requires that clinicians complete peer reviews within 120 days.

Concur

Response: The following tracking system has been implemented to ensure that each peer review case will be completed within 120 days: (1) the QM Program Support Assistant will contact the Administrative Officer of the appropriate department at day 30 and day 40 (this is 30 days and 40 days after the peer review case was given to the AO of a dept. by the QM staff to assign a physician to complete the peer review case), (2) the AO of the dept. will then contact the physician that he or she has assigned to the peer review case to check on the progress of the completion of the peer review case and to remind the MD of their deadline to complete the peer review process within 45 days, (3) the AO will email or call the QM Program Support Assistant or QM staff with the update, (4) the AO will contact the QM staff when the peer review is completed. **Action to be completed by January 1, 2008.**

*The Peer Review Process Description sheet will be available upon request.

Recommendation 3. We recommended that the VISN Director ensure that the System Director requires concurrent review of blood and blood product use.

Concur

Response: Since the OIG visit in August 2007, the Blood Transfusion Review Process is now current through July 2007, except for the month of June is not completed as of 9/21/07. There are five blood transfusion product reviews, which are in the process of peer review. Note: all blood transfusion product reviews met criteria for the months of February, March, and May.

The following list contains the month and the number of reviews that did not meet criteria by the QM RN reviewer and the pathologist, and currently, a letter is being sent to the attending physician requesting a written response regarding the reason for the blood product transfusion order:

- April – one blood transfusion review.
- July – three blood transfusion reviews.

The following list contains the month and the number of reviews that did not meet criteria by the QM RN:

- July – one blood transfusion review to be reviewed by the pathologist.

Action to be completed by November 30, 2007.

*The Blood Transfusion Review Process sheet will be available upon request.

Recommendation 4. We recommended that the VISN Director ensure that the System Director requires that the ACOS/R&D review and approve all scopes of practice for system personnel engaged in research activities.

Concur

Response: Members of the Research staff involved in the protocol submission process and personnel credentialing process met on Friday, August 25, to discuss the findings of the CAP team, to examine how this could have occurred, and to ensure that appropriate processes and procedures were clarified and in place for future compliance. This error appears to have occurred due to a lapse of process and an isolated example of miscommunication regarding the appropriate flow of the scope of practice paperwork. In the future, the IRB coordinator will collect competed forms from the PI and will do an initial check to see that both the employee and the PI have signed the scope of practice form. The IRB coordinator will give all credentialing information, including the scope of practice form, to the credentialing coordinator who will review the form for completeness and will route to the ACOS/Research for review and signature. After receipt of the ACOS's signature, the original scope of practice form will be placed in the employee's research credentialing

folder, and the IRB coordinator will be advised that the scope of practice is complete with all signatures. No protocol will be considered processed until this check and balance process has been completed. We would like to close this recommendation. **Action completed on August 25, 2007.**

OIG Contact and Staff Acknowledgments

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