Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 08-01088-111

Combined Assessment Program Review of the Chalmers P. Wylie Independent Outpatient Clinic Columbus, Ohio

April 10, 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 3–7, 2008, the OIG conducted a Combined Assessment Program (CAP) review of the Chalmers P. Wylie Independent Outpatient Clinic (the clinic), Columbus, OH. 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 107 clinic employees. The clinic is part of Veterans Integrated Service Network (VISN) 10.

Results of the Review

The CAP review covered five operational activities. We identified the following organizational strengths and reported accomplishments:

- Temperature Monitoring.
- Ferrous Metal Detector Initiative.

We made recommendations in two of the activities reviewed—QM and Pharmacy Operations. For these activities, the clinic needed to:

- Document Peer Review Committee (PRC) discussions of recommendations for improvement in clinical practice, document provider responses to peer review recommendations, and record supervisory feedback.
- Ensure that approved provider privileges are not greater than the capability of the clinic.
- Implement a moderate sedation monitoring process.
- Provide and document annual training for controlled substances inspectors.

The clinic complied with selected standards in the following three activities:

- Computerized Patient Record System (CPRS) Business Rules.
- Environment of Care (EOC).
- Survey of Healthcare Experiences of Patients (SHEP).

This report was prepared under the direction of Randall Snow, Associate Director, Washington, DC, Office of Healthcare Inspections.

Comments

The VISN and Clinic Directors agreed with the CAP review findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 12–15, for the full text of the Directors' comments.) We will follow up on the planned 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 clinic is an ambulatory care facility located in Columbus, OH, that provides a broad range of outpatient health care services. Outpatient care is also provided at four community based outpatient clinics in Grove City, Marion, Newark, and Zanesville, OH. The clinic is part of VISN 10 and serves a veteran population of about 150,000 throughout 13 counties in central Ohio. The clinic will move to a new, larger building in another location in the fall of 2008.

Programs. The clinic supports programs in medicine, surgery, extended care, and ambulatory care. The continuum of patient services is ensured through primary care, nursing home care, hospital-based home care, and mental health services. Inpatient treatment is provided via contract with OhioHealth for urgent/emergent care and by referral to VISN 10 medical centers for elective care.

Affiliations and Research. The clinic is affiliated with Ohio State University's Colleges of Pharmacy, Social Work, Dentistry, Optometry, and Nursing. It is also affiliated with the University of Iowa's College of Pharmacy and Butler University's College of Pharmacy and Health Sciences. An important area of research is the Chronic Homeless Initiative; research is done in conjunction with the Cincinnati VA Medical Center and the University of Cincinnati.

Resources. In FY 2007, medical care expenditures totaled $115 million, which included a $20 million activation expense for the new ambulatory care center. The FY 2008 medical care budget is $112.8 million. FY 2007 staffing was 465.4 full-time employee equivalents (FTE), including 40.2 physician and 84.8 nursing FTE.

Workload. In FY 2007, the clinic treated 29,648 unique patients and provided 2,008 inpatient days of care through its contract with OhioHealth. The clinic provided 9,009 inpatient days in the community nursing home care unit. The inpatient care workload totaled 630 discharges, and the average daily census, including nursing home patients, was 30. Outpatient workload totaled 302,898 visits.

Objectives and Scope

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

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

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

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

- CPRS Business Rules.
- EOC.
- Pharmacy Operations.
- QM.
- SHEP.

The review covered clinic operations for FY 2007 and FY 2008 through March 7, 2008, and was done in accordance with OIG standard operating procedures for CAP reviews. We also followed up on select recommendations from the prior CAP review of the clinic (*Combined Assessment Program Review of the Chalmers P. Wylie VA Outpatient Clinic, Columbus, Ohio,* Report No. 02-01430-50, January 23, 2003). The clinic had corrected all health care related conditions identified during the prior CAP review; therefore, we consider these issues closed.

During this review, we also presented fraud and integrity awareness briefings for 107 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

Temperature Monitoring

The Chief of Pharmacy took the lead in implementing a wireless computerized remote temperature monitoring, recording, and alert system. The system wirelessly monitors temperatures of refrigerators, freezers, and other equipment where temperature monitoring is critical. Alerts from the system prevent product loss, ensure quality, and contribute to patient safety. The clinic operates on a Monday through Friday schedule. Monitoring temperatures during off hours and over the weekends had presented a challenge in quality control and resulted in a loss of revenue. The remote temperature monitoring system has improved quality control and patient safety and has decreased loss of revenue.

Ferrous Metal Detector Initiative

A ferromagnetic object taken into the magnetic resonance imaging (MRI) magnet's stray field can be pulled into the magnet's core at high speed causing serious injury, damage, and downtime. This phenomenon is known as the "projectile effect." Serious incidents of the "projectile effect" have been reported by numerous medical institutions and have involved such objects as gas cylinders, chairs, respirators, intravenous poles, and smaller objects. Such occurrences can result in the loss of imaging time due to repairs and/or result in injury to patients or staff. The Radiology Supervisor recognized the need to initiate ferrous metal screening and installed two detectors in the MRI suite. The detectors are used as ancillary screening devices to improve patient safety by supplementing traditional safety programs, training, and primary screening methods.

Results

Review Activities With Recommendations

Quality Management

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

The QM program was generally effective in providing oversight of the quality of care in the clinic. However, we identified the following areas that needed improvement.

Peer Review. The peer review process did not include all components required by the Veterans Health Administration (VHA).[1] Peer review is a confidential, non-punitive, and systematic process to evaluate the quality of care at the individual provider level. The peer review process includes an initial review by a peer of the same discipline to determine the level of care,[2] with subsequent PRC evaluation and concurrence with the findings. The clinic completed all peer reviews within the required timeframes.

VHA requires that the PRC document discussions and analyze trends and findings to offer suggestions for improving clinical practices. The PRC minutes contained discussion of individual peer reviews; however, there was no documentation of discussion of recommendations for improvement in clinical practice.

When peer review determines that a case rises to a Level 2 or 3, the involved provider should be offered the opportunity to submit further documentation or appear before the PRC. We reviewed PRC minutes for FY 2007; none of the minutes contained documentation of a provider's response or appearance before the PRC.

Supervisory feedback is also required when peer review determines a case to be a Level 2 or 3. Supervisors must discuss the peer review determinations with providers to ensure that the appropriate non-disciplinary actions are

[1] VHA Directive 2004-054, *Peer Review for Quality Management*, September 29, 2004.
[2] Peer review levels: Level 1 – Most experienced, competent practitioners would have managed the case similarly; Level 2 – Most experienced, competent practitioners might have managed the case differently; Level 3 – Most experienced, competent practitioners would have managed the case differently.

taken to improve the quality of health care delivered. A written report of this feedback and the completed actions should be submitted to the PRC. Feedback and completed actions were not documented in the PRC minutes.

Clinical Privileging. Clinical privileging includes a series of activities designed to collect relevant data and the decision-making process to assure that qualified health care professionals are providing the appropriate care in the appropriate setting. We reviewed the privileges granted to six providers, three of whom were surgeons. The surgeons had been granted privileges to perform surgery beyond the capability of the clinic.

Moderate Sedation. Moderate sedation is a form of drug-induced depression of consciousness used to decrease pain and anxiety and to improve comfort for patients undergoing procedures or diagnostic treatments. Because of potential risk, VHA requires the monitoring of compliance with defined protocols in all areas where moderate sedation is given.[3] The Operative and Invasive Procedure Committee is the local oversight committee for analyzing data related to moderate sedation. We reviewed the committee minutes for FY 2007, and no moderate sedation data had been reported. Local clinic practice was to not record the use of moderate sedation or the use of reversal agents unless the reversal agents were used to rescue a patient. The routine use of reversal agents is not normally considered an adverse event and is considered the standard of practice in many communities.

Recommendation 1 We recommended that the VISN Director ensure that the Clinic Director requires that the PRC document discussions of recommendations for improvement in clinical practice, document all follow-up provider responses to Level 2 or 3 peer reviews, and record written feedback from supervisors.

Recommendation 2 We recommended that the VISN Director ensure that the Clinic Director requires that providers are privileged to perform procedures that are within the capability of the clinic.

Recommendation 3 We recommended that the VISN Director ensure that the Clinic Director requires implementation of a process for monitoring moderate sedation.

[3] VHA Directive 2006-023, *Moderate Sedation by Non- Anesthesia Providers*, May 1, 2006.

The VISN and Clinic Directors concurred with the findings and recommendations and have implemented action plans to standardize PRC meeting minutes to document discussions concerning improvements in clinical practice, provider responses to Level 2 and 3 peer reviews, and supervisory feedback. The clinic has revised core privileges to match the clinic's capabilities and has instituted a process for monitoring compliance with moderate sedation protocols. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

Pharmacy Operations

The purpose of this review was to evaluate whether the clinic had adequate controls to ensure the security and proper management of controlled substances and the pharmacy's internal physical environment. We also evaluated whether clinical managers had processes in place to monitor patients prescribed multiple medications to avoid polypharmacy, especially in vulnerable populations.

We reviewed VHA regulations governing pharmacy and controlled substances security, and we assessed whether the clinic's policies and practices were consistent with VHA regulations. We inspected the outpatient pharmacy for security, EOC, and infection control concerns, and we interviewed Pharmacy Service and Police and Security Service personnel. Additionally, we evaluated whether clinical pharmacists monitored patients prescribed multiple medications to avoid polypharmacy.

Pharmacy Controls. The clinic had appropriate policies and procedures to ensure the security of the pharmacy and controlled substances. Controlled substances inspections were conducted according to VHA regulations, and managers reported all controlled substance diversions or suspected diversions to the OIG. The pharmacy's internal EOC was secure, clean, and well maintained.

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. Elderly patients and mental health patients are among the most vulnerable populations for polypharmacy.

Managers had developed effective processes to ensure that clinical pharmacists identified patients who were prescribed multiple medications, reviewed their medication regimens to avoid polypharmacy, and advised providers as appropriate.

Training. Annual training for inspectors was not consistently achieved. VHA policy[4] requires all new and current pharmacy employees to maintain an annual program for orientation and training. We reviewed the training records of seven inspectors, including the coordinator, and found that only two of the seven records documented the required annual training.

Recommendation 4 We recommended that the VISN Director ensure that the Clinic Director requires that annual training for controlled substances inspectors is conducted and documented.

The VISN and Clinic Directors concurred with the finding and recommendation and have scheduled annual training for controlled substances inspectors. The implementation plans are acceptable, and we will follow up on the planned actions until they are completed.

Review Activities Without Recommendations

Environment of Care

The purpose of this review was to determine if the clinic maintained a safe and clean health care environment. The clinic is required to provide a comprehensive EOC program that fully meets VHA National Center for Patient Safety, Occupational Safety and Health Administration, and Joint Commission[5] standards. The infection control program was evaluated to determine compliance with VHA directives based on the management of data collected and processes in which the data was used to improve performance.

We inspected the operating room (OR); Supply, Processing, and Distribution (SPD); the dental clinic; infusion/oncology; the canteen; and the urgent care clinic. The clinic

[4] VHA Handbook 1108.1, *Controlled Substances (Pharmacy Stock),* October 4, 2004.
[5] The Joint Commission was formerly the "Joint Commission on Accreditation of Healthcare Organizations," also known as JCAHO.

maintained a generally clean environment. The infection control program monitored and reported data to clinicians for implementation of quality improvements. Safety guidelines were met, and risk assessments complied with VHA standards.

Mental Health Clinic. Clinic managers implemented mental health EOC safety standards in the mental health clinic. These standards are normally applied to locked inpatient psychiatric units. The clinic conducted a risk assessment and abatement survey and identified environmental hazards that could possibly pose a threat to suicidal patients. The clinic is in the process of eliminating the identified hazards.

Dental Clinic. We found that the dental clinic stored sterile instruments in an unlocked room in a hall and dirty instruments in an unlocked cart in the same hall. This allowed unauthorized personnel to access the sterile and dirty instruments. The clinic corrected this deficiency while we were onsite, and we consider the issue closed.

We made no recommendations.

Computerized Patient Record System Business Rules

The health record, as defined by VHA policy,[6] includes the electronic medical record and the paper record, combined, 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.

A communication (software informational patch USR*1*26) was sent from the VHA Office of Information (OI) on October 20, 2004, to all medical centers, providing guidance on a number of issues related to the editing of electronically signed documents in the electronic medical records system. The OI 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." 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.

[6] VHA Handbook 1907.01, *Health Information Management and Health Records*. August 25, 2006.

Business rules define what functions certain groups or individuals are allowed to perform in the medical record. OI has recommended institution of a VHA-wide software change that limits the ability to edit a signed medical record document to a facility's Privacy Officer.

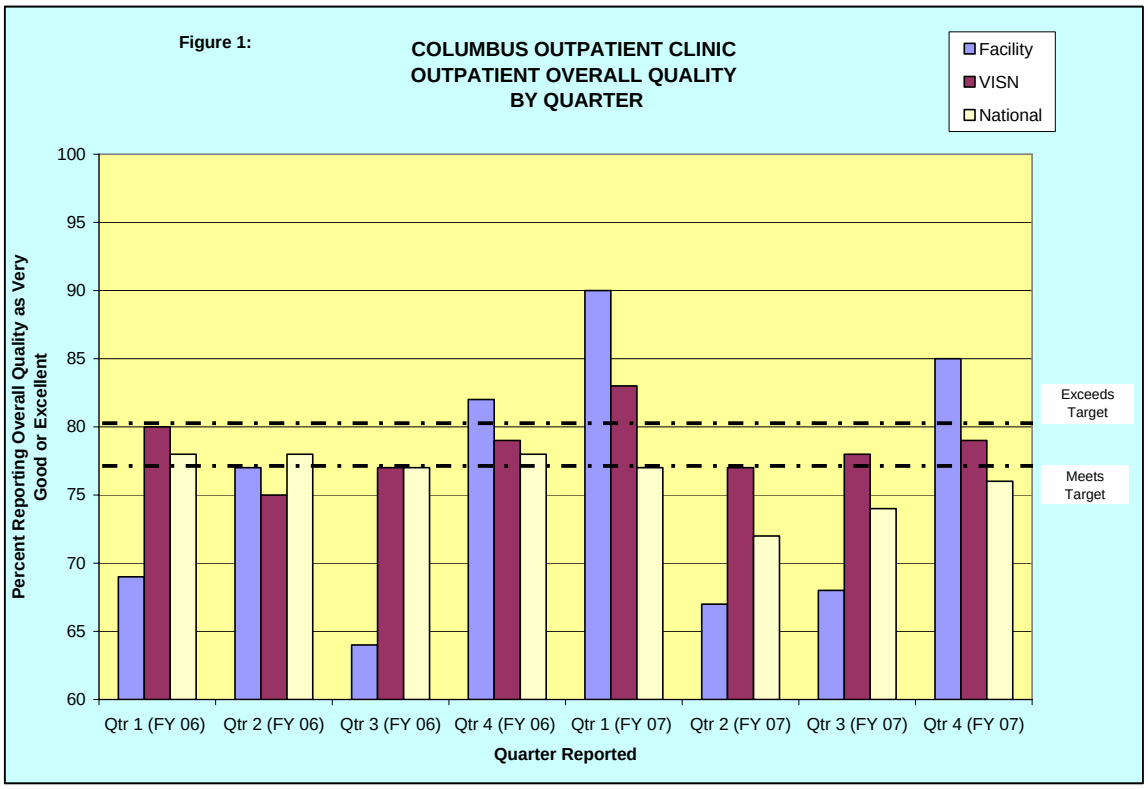
We reviewed VHA and clinic information and technology policies and interviewed Information Resource Management Service staff. We found that all of the business rules provided to the OIG inspector were in compliance with VHA Handbook 1907.1. The clinic has a multidisciplinary Health Information Team, which meets monthly to address issues raised during day-to-day operations and to discuss progress on implementation of OI informational patches.

We made no recommendations.

Survey of Healthcare Experiences of Patients

The purpose of this review was to assess the extent that the clinic used the quarterly/semi-annual survey report results of patients' health care experiences 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 performance measure results for patients reporting overall satisfaction of "very good" or "excellent" at 76 percent for inpatients and 77 percent for outpatients.

Figure 1 on the next page shows the clinic's SHEP performance measure results for outpatients.



The clinic met or exceeded the established target for 3 of the last 8 quarters of available data for outpatient overall quality. The clinic gathers patient satisfaction data through several internal mechanisms—the Patient Advocate Tracking System; Quick Cards; and Red, White, and Blue Surveys. Analysis of the collected data is reported to the Executive Management Board, the Performance Improvement Committee, the Chief of Medicine, and the Clinic Director's staff.

Two significant changes have resulted from the above mechanisms. Trends showed persistent patient complaints about the communication skills of providers and telephone waiting times. Specialized training to improve communication between patient and provider was offered, resulting in a 95 percent reduction in complaints about provider communication. A call center was established that provides a nurse advice line, a pharmacy line, and an appointment line. This has resulted in the near elimination of "dropped calls" and has reduced the average patient service call time to 2.5 minutes. Since implementation of the call center, patient complaints have been reduced from an average of nine per quarter to less than one per quarter.

The clinic closely monitored patient satisfaction scores and implemented timely changes to address identified concerns. Therefore, we made no recommendations.

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: March 28, 2008

From: Network Director, VA Healthcare System of Ohio (10N10)

Subject: **Combined Assessment Program Review of the Chalmers P. Wylie Independent Outpatient Clinic, Columbus, Ohio**

To: Director Healthcare Inspections Division (54DC)

Director, Management Review Service (10B5)

I have reviewed the Combined Assessment Program Review of the Columbus OPC. I agree with the four recommendations made by the Office of Inspector General.

Comments have been made on each recommendation. Recommendation numbers 1, 2, and 3 have been completed. Recommendation 4 is expected to be completed by April 17, 2008.

(original signed by:)

JACK G. HETRICK, FACHE

Attachment: Comments

Clinic Director Comments

Department of Veterans Affairs **Memorandum**

Date: March 28, 2008

From: Director, Chalmers P. Wylie Independent Outpatient Clinic (757)

Subject: **Combined Assessment Program Review of the Chalmers P. Wylie Independent Outpatient Clinic, Columbus, Ohio**

To: Network Director (10N10)

Please see attached comments in response to OIG findings and recommendations.

(original signed by:)

LILIAN T. THOME, MD

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 Clinic Director requires that the PRC document discussions of recommendations for improvement in clinical practice, document all follow-up provider responses to Level 2 or 3 peer reviews, and record written feedback from supervisors.

Concur

The Peer Review Committee has implemented a standardized format for minutes to include agenda items; discussion with recommendations for improvement in clinical practice; action and/or follow-up items, i.e., provider responses to Level 2 or 3 peer reviews; responsible party; and due date for action items. **Completed March 20, 2008**.

Recommendation 2. We recommended that the VISN Director ensure that the Clinic Director requires that providers are privileged to perform procedures that are within the capability of the clinic.

Concur

Core privileges have been revised to reflect the capability of the facility. **Completed March 7, 2008**.

Recommendation 3. We recommended that the VISN Director ensure that the Clinic Director requires implementation of a process for monitoring moderate sedation.

Concur

A process for monitoring compliance with defined protocols for moderate sedation and the use of reversal agents has been instituted. This data will be reported to the Performance Improvement Council. **Completed March 7, 2008**.

Recommendation 4. We recommended that the VISN Director ensure that the Clinic Director requires that annual training for controlled substances inspectors is conducted and documented.

Concur.

Annual training for the Controlled Substance Inspectors has been implemented. **Expected Date of Completion: April 17, 2008.**

OIG Contact and Staff Acknowledgments

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