Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 08-00777-200

Combined Assessment Program Review of the Miami VA Healthcare System Miami, Florida

September 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 May 5–9, 2008, the OIG conducted a Combined Assessment Program (CAP) review of the Miami VA Healthcare System (the system). 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 312 employees. The system is part of Veterans Integrated Service Network (VISN) 8.

Results of the Review

The CAP review covered seven operational areas and activities. We identified the following two activities as organizational strengths:

- Electronic medical record (EMR) business rules.
- Prosthetic modular foot design and development.

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

- Improve the coordination of system-wide performance improvement (PI) activities.
- Evaluate and disclose adverse events, in accordance with Veterans Health Administration (VHA) policy.
- Require nursing staff to increase patient monitoring on the locked mental health unit, in accordance with the risk abatement plan.
- Assure the security of confidential patient information.

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

- Patient Satisfaction.
- Pharmacy Operations.

For the other review area, discharge instructions, the system developed a template to clarify the instructions while we were onsite; therefore, we made no recommendations.

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

Comments

The VISN and System Directors agreed with the findings and recommendations and submitted acceptable improvement plans. (See Appendixes A and B, pages 12–16, for the full text of the Directors' comments.) We will follow up on all 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 is a tertiary care facility that provides a broad range of inpatient and outpatient health care services. Outpatient care is also provided at nine community based outpatient clinics in Coral Springs, Deerfield Beach, Hollywood, Homestead, Key Largo, Key West, Miami, Oakland Park, and Pembroke Pines, FL. The system is part of VISN 8 and serves a population of about 285,000 throughout Broward, Dade, and Monroe counties.

Programs. The system provides general medical, surgical, and psychiatric services. It has 191 hospital beds and 120 nursing home beds.

Affiliations and Research. The system is affiliated with the University of Miami's Miller School of Medicine, Barry University, Nova Southeastern University, Miami Dade College, and Florida International University. It provides training for 150 medical residents. In fiscal year (FY) 2007, the system's research program had 250 projects and a budget of $8.7 million. Important areas of research include geriatrics, spinal cord injury, and prostate cancer.

Resources. In FY 2007, medical care expenditures totaled $277.5 million. The FY 2008 medical care budget is $300.8 million. FY 2007 staffing was 2,301 full-time employee (FTE) equivalents, including 141 physician and 649 nursing FTE.

Workload. In FY 2007, the system treated 53,043 unique patients and provided 41,624 inpatient days in the hospital, 42,211 inpatient days in the nursing home and intermediate care units, and 19,376 days of care in the psychiatric residential rehabilitation programs. The inpatient care workload for all programs totaled 6,723 discharges, and the average daily census was 283. Outpatient workload totaled 603,728 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 seven areas and activities:

- Discharge Instructions.
- EMR Business Rules.
- Environment of Care (EOC).
- Patient Satisfaction.
- Pharmacy Operations.
- Prosthetic Modular Foot Design and Development.
- QM.

The review covered system operations for FY 2006, FY 2007, and FY 2008 through May 5, 2008, and was done in accordance with OIG standard operating procedures for CAP reviews. We also followed up on selected health care recommendations from our prior CAP review of the system (*Combined Assessment Program Review of the VA Medical Center, Miami, Florida,* Report No. 05-00502-171, July 8, 2005). The system 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 312 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. The activities in the "Review Activities Without Recommendations" and "Other Review Area" sections have no findings requiring corrective actions or further follow-up.

Organizational Strengths

Electronic Medical Record Business Rules

The system had a unique collaborative approach to comply with VHA guidelines for the EMR. Business rules define which groups or individuals are allowed to edit, amend, or delete documentation in EMRs. The health record, as defined by VHA,[1] 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.

A multidisciplinary committee with representatives from Health Information Systems, Medicine, Nursing, QM, and other disciplines regularly reviewed EMR business rules for appropriateness. The roles of the Privacy Officer (PO) and the Chief of Health Information Management Service were well defined by policy. Documentation that required editing, deletion, or retraction was tracked and evaluated on a regular basis. We found that all of the business rules were in compliance with VHA Handbook 1907.01.

Prosthetic Modular Foot Design and Development

In 2007, the system's Lead Orthotic Prosthetist[2] invented a prosthetic modular foot for Symes[3] amputees. The March 2007 *O&P Almanac*[4] featured an article titled "Solutions for the Symes Foot," which highlighted the development of the prosthesis, its patient functionality, and the expertise of the system's clinical staff. The device was showcased at the American Academy of Orthotists and Prosthetists 34th Annual Meeting and Scientific Symposium where it was recognized for its design and ingenuity. This

[1] VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006.
[2] One who designs and fits artificial limbs.
[3] Symes amputation is amputation of the foot from the lower leg.
[4] O&P stands for orthotics and prosthetics. The *O&P Almanac* is published by the American Orthotic & Prosthetic Association.

prosthesis has greater energy storage/release capabilities, reduces the risk of biomechanical failure, weighs less, and accommodates more commercially available shoes than many other Symes prosthetic foot and socket technologies. The custom cushion liners relieve pressure points on the residual limb and increase patient compliance with use.

Results

Review Activities With Recommendations

Quality Management

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

The QM program was generally effective in its monitoring of the quality of patient care in the system, and managers were supportive of QM efforts. Credentialing and privileging, mortality analyses, peer review, patient complaints, patient safety, medication reconciliation, utilization management, blood products usage, operative and other procedures reviews, resuscitation outcomes, restraint and seclusion, medical records, and system redesign/patient flow were monitored effectively. However, we identified two areas that needed strengthening.

Performance Improvement Coordination. We found that the Leadership Council (LC), as the system's governing body, needed to improve the coordination of system-wide PI activities, as required by The Joint Commission and local policy.

The system's PI Committee (PIC) was responsible for collecting and evaluating PI data from other system committees and for reporting important system-wide PI issues to the LC. However, the PIC had not met since August 2007 when the Quality Manager (who was also the PIC Chairperson) left her position. In the PIC's absence, the

LC assumed responsibility for these functions. However, LC minutes did not always reflect discussion of the issues nor did they consistently reflect corrective actions, responsible parties, or target dates for completion. In addition, LC minutes did not reflect whether action items were followed up at subsequent meetings. Without coordinated efforts and appropriate follow-up, managers could miss opportunities to improve performance.

While we were onsite, senior managers told us that they planned to reinstitute the PIC. In addition, managers provided a draft of proposed changes to LC structure to improve the coordination and follow-up of system-wide PI actions.

Adverse Event Disclosure. The system did not evaluate cases for possible disclosure, as required by VHA[5] and local policy. Clinical disclosure is an informal process to discuss harmful events with patients and/or their families; physicians document clinical disclosure in progress notes. Institutional disclosure is a more formal process used in cases of serious injury, death, or potential legal liability and includes an apology, compensation information, and procedures available to request compensation.

We identified 12 cases involving adverse events that occurred in FY 2007 and had not been evaluated for disclosure. Managers told us that the system had recently drafted a policy. As of March 2008, four cases had been evaluated for disclosure, and three cases had been disclosed to patients and/or their families. While there appears to be some improvement, not enough time has elapsed to determine whether the new policy has effectively addressed the condition. Without a defined process for adequate evaluation of events that could potentially require disclosure, managers could not be assured that patients received important medical and legal information needed to make decisions.

Recommendation 1 We recommended that the VISN Director ensure that the System Director reinstitutes the PIC and implements proposed changes to the LC to improve the coordination of system-wide PI activities.

[5] VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, October 27, 2005.

The VISN and System Directors agreed with the finding and recommendation and reported that a new governance framework (council/committee structure) has been implemented and that a patient-centered Executive Leadership Board, which incorporates Baldrige principles, has been established. The corrective actions are acceptable, and we consider this recommendation closed.

Recommendation 2 We recommended that the VISN Director ensure that the System Director fully implements the policy for evaluation and disclosure of adverse events and tracks compliance with VHA policy.

The VISN and System Directors agreed with the finding and recommendation and reported that the Preventative Ethics Team, in collaboration with Risk Management, QM, and clinicians, suggested revisions to the disclosure policy. A process to capture all incidents and disclose them appropriately has been recommended. Disclosures will be documented using the disclosure progress note template. Once leadership has approved the recommended changes, education for clinicians will be implemented. Disclosure reports will be reported to leadership quarterly via the Joint Commission/PI Dashboard. We will follow up on the planned actions until they are completed.

Environment of Care

The purpose of this review was to determine if VHA medical centers maintain a safe and clean health care environment. Facilities are required to provide an EOC program that fully meets VHA, Occupational Safety and Health Administration, and Joint Commission standards. We evaluated the infection control (IC) program to determine compliance with VHA directives based on the management of data collected and processes in which the data was used to improve performance. Additionally, we reviewed the locked acute inpatient mental health unit to determine if managers identified and mitigated environmental hazards that pose a threat to patients and to ensure that staff received specialized training.

We inspected the acute inpatient units on 11AB and 12AB; the medical intensive care, surgical intensive care, and intermediate care units; the locked inpatient mental health unit; the substance abuse rehabilitation unit; the emergency room; the chemotherapy suite; and the dialysis unit.

The system was generally clean and well maintained. The IC program monitored and reported data to clinicians for implementation of quality improvements, and appropriate mental health unit staff received the required safety training. However, we identified issues with safety on the locked mental health unit, patient privacy, and routine maintenance of ventilation units that required management attention.

Safety Risk Abatement. The system's Multidisciplinary Safety Inspection Team conducted rounds on the locked inpatient mental health unit and completed the "Mental Health Environment of Care Checklist" (MHEOCC),[6] as required by VHA. We received an abatement tracking plan[7] that identified 23 MHEOCC items requiring corrective action. We were told that many of these conditions could not be addressed immediately because the system needed time and resources to resolve the problems. An interim safety measure requiring nursing staff to conduct hourly patient monitoring was initiated; however, we found that for the period January–April 2008, increased monitoring was not consistently conducted.

Patient Privacy. We found two unattended computers in patient care areas with patient information displayed on the monitors. The security of confidential patient information is required under the Health Insurance Portability and Accountability Act to protect patient privacy.

Dusty Ventilation Outlets. Ventilation outlets were not cleaned according to Environmental Management Service standard operating procedures. During environmental rounds, we found dust in air ventilation outlets on several inpatient units. Controlling dust emissions reduces patient risk for dust-related respiratory problems. Before we left site, managers provided us with an action plan to ensure scheduled cleaning of ventilation outlets. Therefore, we made no recommendation for this issue.

Recommendation 3 We recommended that the VISN Director ensure that the System Director requires nursing staff to conduct and document patient monitoring every hour on the locked

[6] A tool used for the purpose of assessing environmental risks and eliminating factors that could contribute to attempted suicide or suicide of a patient or harm to staff members.
[7] A template used for tracking progress towards eliminating environmental risks.

mental health unit, in accordance with the risk abatement plan.

The VISN and System Directors agreed with the finding and recommendation and reported that an hourly patient count checklist has been established and that supervisory responsibility for monitoring the process has been assigned. The system has demonstrated 100 percent compliance with documentation of patient monitoring since our visit. The corrective action is acceptable, and we consider this recommendation closed.

Recommendation 4 We recommended that the VISN Director ensure that the System Director requires that security of confidential patient information is maintained.

The VISN and System Directors agreed with the finding and recommendation and reported that Information Security Officer (ISO) and PO reviews will be aggregated and analyzed quarterly. Corrective actions will be instituted and reported to the EOC Safety Committee. The ISO and the PO scheduled additional cyber security and privacy training during the month of August for staff who had not yet completed their annual training. We will follow up on the planned actions until they are completed.

Review Activities Without Recommendations

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 survey data to improve patient care.

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." Health care systems are expected to address areas in which they are underperforming. The purpose of this review was to assess the extent that the system used SHEP data to improve patient care and services.

Figures 1 and 2 on the next page show the system's patient satisfaction performance measure results for inpatients and outpatients, respectively.

Figure 1:

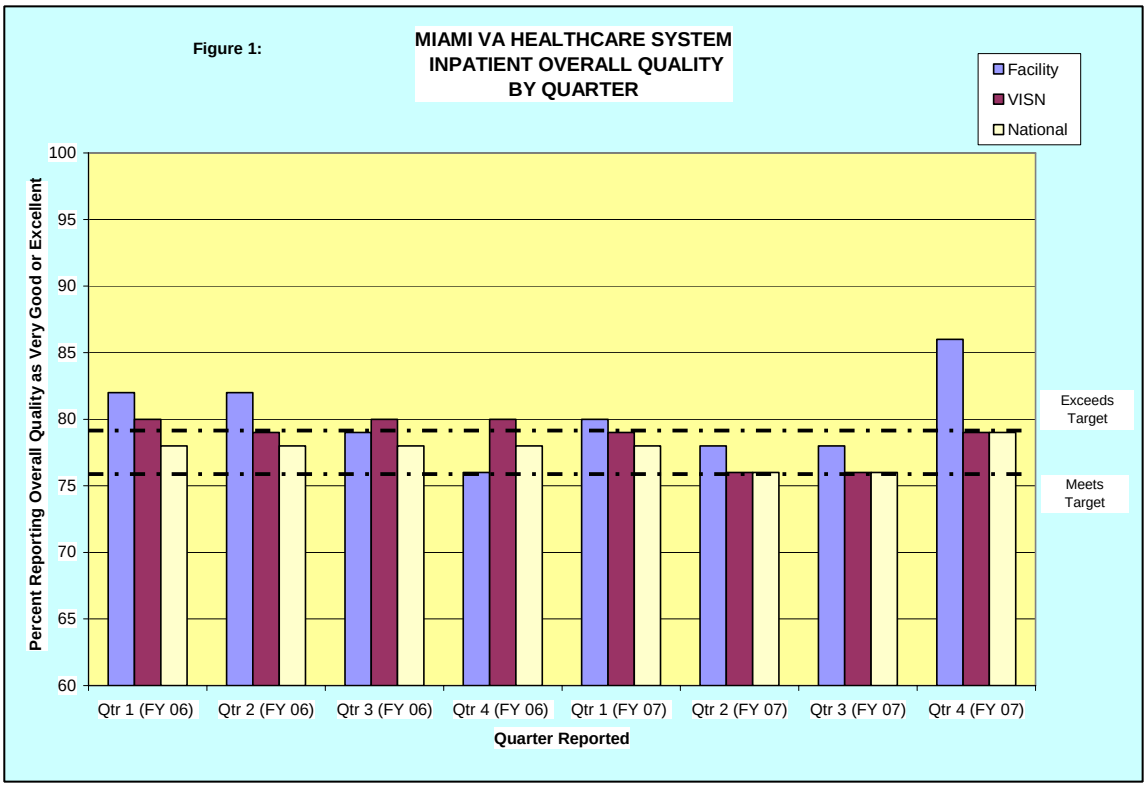
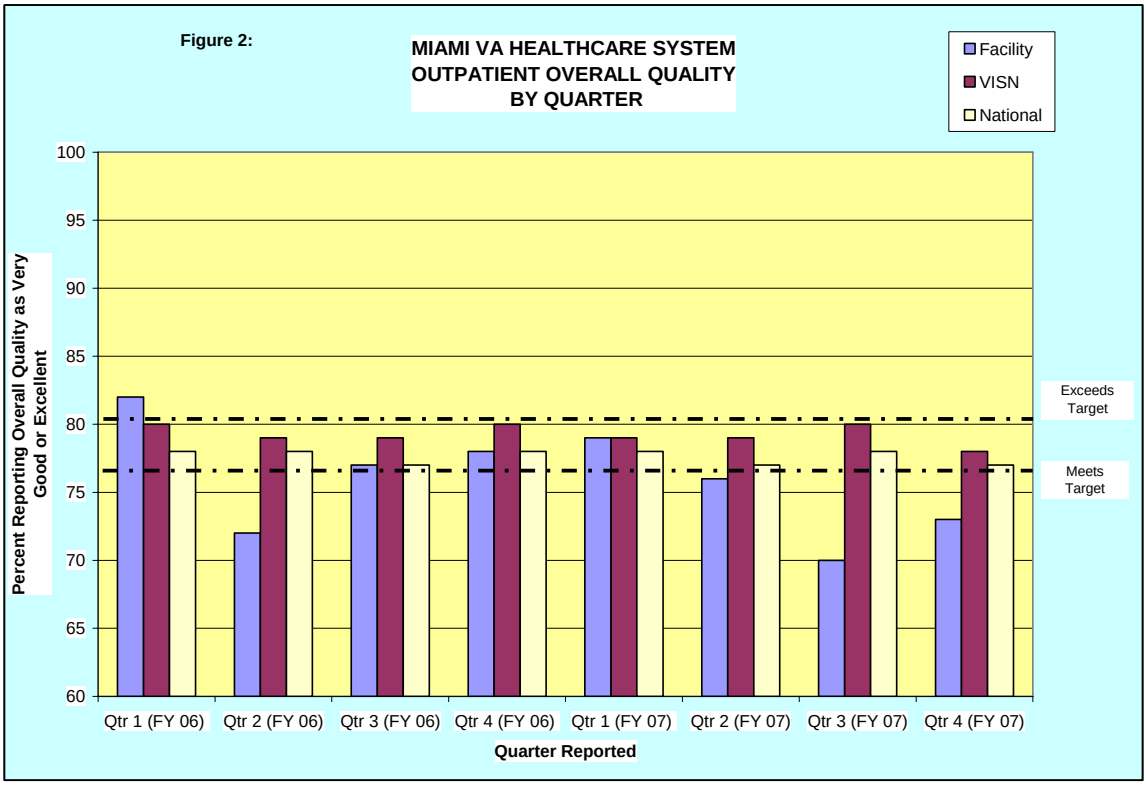


Figure 2:



The system met or exceeded the established target for inpatient overall quality for all of the last 8 quarters of available data. However, the system only met the established target for 4 of the last 8 quarters of available data for outpatient overall quality. The system had a multidisciplinary Customer Service Committee that analyzed and reported SHEP survey results. The committee identified opportunities to improve patient satisfaction by increasing access to care and decreasing wait times in the outpatient clinics. Managers also hired three new patient advocates for the outpatient clinics. Therefore, we made no recommendations.

Pharmacy Operations

The purpose of this review was to evaluate whether VA medical facilities had adequate controls to ensure the security and proper management of controlled substances and to evaluate the pharmacies' internal physical environments. We also evaluated whether clinical managers had processes in place to monitor patients who were prescribed multiple medications.

We reviewed VHA regulations[8] governing pharmacy and controlled substances security, and we assessed whether the system's policies and practices were consistent with VHA regulations. We inspected inpatient and outpatient pharmacies for security, EOC, and IC concerns, and we interviewed appropriate Pharmacy Service and Police and Security Service personnel as necessary. We also interviewed the Controlled Substances Coordinator (CSC) and the Chief of Pharmacy Service to determine if clinical pharmacists monitored patients for polypharmacy.

Pharmacy Controls. Our review showed that the system had appropriate policies and procedures to ensure the security of the pharmacies and controlled substances. Controlled substances inspections were conducted according to VHA regulations. The CSC and controlled substance inspectors (CSIs) received appropriate training to execute their duties. The CSIs rotated to different areas and conducted random inspections on different days each month. We also found that managers reported all controlled substances diversions or suspected diversions to the OIG. The pharmacies' internal physical environments were secure, clean, and well

[8] 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.

maintained. The clean room,[9] where sterile intravenous medications were prepared, complied with VHA regulations[10] and IC standards.

Polypharmacy. Our review showed that clinical pharmacists appropriately identified patients who were prescribed multiple medications. Pharmacological regimens involving multiple medications are often necessary to prevent and treat disease states; however, excessive use of medications can result in adverse reactions and an 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.[11] We found that the system's clinical pharmacists routinely assessed patients for polypharmacy, in accordance with guidelines.

VISN performance data showed that the system ranked above 90 percent in polypharmacy prevention in the 3rd quarter of FY 2007 and in the 1st and 2nd quarters of FY 2008. We made no recommendations.

Other Review Area

Discharge Instructions

During the course of our CAP review, we found that the printed physician discharge instruction sheet provided to patients could compromise patient safety. The physician discharge instruction template that was completed at the time of discharge had a section called "other recommended medications" that still listed inpatient medications, some of which had been discontinued. These conflicting instructions could be confusing to patients, thereby increasing the probability of non-compliance or an adverse drug event. The system took action to correct the physician discharge instruction template while we were onsite. Therefore, we made no recommendations.

[9] A room in the inpatient pharmacy where the concentration of airborne particles is controlled by proper construction, temperature, humidity, and air pressure.
[10] VHA Handbook 1108.6.
[11] Yvette C. Terrie, BSPharm, RPh, "Understanding and Managing Polypharmacy in the Elderly," *Pharmacy Times*, December 2004.

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: August 8, 2008

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

Subject: **Combined Assessment Program Review of the Miami VA Healthcare System, Miami, Florida**

To: Associate Director, St. Petersburg Office of Healthcare Inspections (54SP)

Director, Management Review Service (10B5)

1. I have reviewed and concur with the findings and recommendations in the report of the Combined Assessment Program Review of the Miami VA Healthcare System, Miami, Florida.

2. Corrective action plans have been established with planned completion dates, as detailed in the attached report.

(original signed by:)

Nevin M. Weaver, FACHE

System Director Comments

Department of Veterans Affairs **Memorandum**

Date: August 8, 2008

From: Director, Miami VA Healthcare System (546/00)

Subject: **Combined Assessment Program Review of the Miami VA Healthcare System, Miami, Florida**

To: Director, VA Sunshine Healthcare Network (10N8)

1. We thank you for allowing us the opportunity to review and respond to the subject report.

2. We concur with the conclusions and recommendations presented by the Office of the Inspector General. We present you with the plans of action designed to correct those areas for which recommendations were provided.

(original signed by:)

MARY D. BERROCAL

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 reinstitutes the PIC and implements proposed changes to the LC to improve the coordination of system-wide PI activities.

Concur

Target Date: September 1, 2008

The Miami VA Healthcare System has approved a new governance framework – Council/Committee Structure that includes the reinstitution of the Performance Improvement Council. The Council was chartered and appointment letters from the System Director were sent on July 31, 2008. A Patient Centered Executive Leadership Board has been established at the center of this framework, incorporating Baldrige principles as a platform for development and deployment.

Recommendation 2. We recommended that the VISN Director ensure that the System Director fully implements the policy for evaluation and disclosure of adverse events and tracks compliance with VHA policy.

Concur

Target Date: December 1, 2008

The Preventive Ethics Team had also identified this opportunity for improvement. It is utilizing the National Center for Ethics ISSUES (e.g., Identify an issue; Study the issue; Select a strategy; Undertake a plan; Evaluate and adjust; Summarize overall effect) approach to identify and address this improvement goal. It has suggested revisions to the Disclosure policy, in collaboration with Risk Management, Quality Management, and clinicians. A process has been recommended to capture all Level 2 and 3 incidents and disclose them appropriately to veterans. Documentation of all disclosures will be made using the Clinical Disclosure Progress Note Title and template. This would provide a means to capture, track, and trend clinical disclosures. Once Leadership has approved the recommended changes, education for clinicians will be implemented. Disclosure reports will be analyzed and aggregated

quarterly and reported to leadership via the Joint Commission/ Performance Improvement Dashboard.

Recommendation 3. We recommended that the VISN Director ensure that the System Director requires nursing staff to conduct and document patient monitoring every hour on the locked mental health unit, in accordance with the risk abatement plan.

Concur

Target Date: May 1, 2008 (completed)

1. An hourly patient count check list has been established and maintained for 24 hours.
2. Each patient will be accounted for (visually) by the RN or designee every hour and the correct code will be entered on the sheet.
3. If a patient is off the unit for any reason, this will also be annotated on the patient count sheet.
4. The Nurse Manager or designee will review the patient count sheets throughout the day and at the end of each shift for completion.
5. At the end of the 24 hour period, the patient count sheets will be maintained in a binder in the nursing station.

Results of the monitoring after the IG visit (5/1/08 – 8/5/08) shows 100 percent of all patient count sheets were accounted for and maintained in a binder in the nursing station.

Recommendation 4. We recommended that the VISN Director ensure that the System Director requires that the security of confidential patient information is maintained.

Concur

Target Date: October 1, 2008

The Information Security Officer (ISO) and Privacy Officer (PO) assess patient care areas on a weekly basis through the Environment of Care Committee Rounds. The weekly rounds are meant to identify potential security violations of VA and local Automated Information Systems (AIS) and Cyber Security policies (for the ISO) and Privacy policies (for the Privacy Officer). In addition to providing an opportunity, in some cases, for immediate corrective action at the time of discovery, findings from the rounds are formally reported to the area managers and/or service chiefs. ISO/PO reviews will be aggregated and analyzed quarterly, corrective actions instituted as appropriate (staff notification, education, etc.), and reported to Environment of Care–Safety Committee. All employees, students, residents, contractors, and volunteers who access VA information systems are required to take training courses in cyber/computer security and privacy annually, as well as signing the VA

National Rules of Behavior. Both the ISO and the PO have scheduled additional training on a weekly basis for the month of August for staff who have not yet completed their training.

OIG Contact and Staff Acknowledgments

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