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8/16/06

From: Director, Washington, D.C. Region Office

Subject: Healthcare Inspections Review and Administrative Case Closure of Alleged Compromised Quality of Care and Alleged Poor / Falsified Documentation at Veterans Affairs Medical Center, Lebanon, PA: Hotline Inspection Project Number: 2006-01144-HL-0325

To: Director, OIG Hotline Division

Background:

The Department of Veterans Affairs (VA) Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) conducted an inspection of a hotline complaint at the VA Medical Center (VAMC), Lebanon, PA. The review was in response to allegations by an anonymous complainant about the quality of medical treatment provided to patients under a recently reorganized management structure at the VAMC.

The purpose of our inspection was to determine if VAMC managers have taken appropriate action regarding the following allegations: 1) a patient was accidentally set on fire during a surgery in the operating room (OR); 2) a patient started to rouse during an emergency surgery because there was insufficient intravenous (IV) solution with anesthesia on hand; 3) nursing staff have been withholding medications they feel are incorrect without consulting with a physician, then hiding the medications in a drawer; 4) a patient received the wrong medication (he was instructed to take the medication anyway but he returned the prescription to the pharmacy at his next clinic appointment. However, when the prescription was returned to the pharmacy, it was missing 3 tablets); 5) untrained staff monitor the narcotics vault and reports are sanitized to eliminate discrepancies; and, 6) some patients in acute care have been wandering from the facility.

Inspection Findings:

Medical Center managers reviewed each allegation and, with the exception of one, were able to associate each allegation with a known incident. VAMC managers provided us with information on these cases and corrective actions taken to prevent further incidents from occurring.

The allegation that could not be associated with a known incident concerned monitoring of narcotics. VAMC managers therefore provided us with applicable policies, procedures and information regarding the medical center's Controlled Substance Inspection Program.

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Allegation 1: A patient was accidentally set on fire during a surgery in the OR.

Our evaluation confirmed that a veteran was involved in an intra-operative fire affecting his face while undergoing an excision for Basil Cell Carcinoma on his nose. To determine how this happened, the Medical Center Director ordered a root cause analysis (RCA). The incident was also reported to the Joint Commission on Accreditation of Hospitals Organization (JCAHO) as a self-reported sentinel event, including an action plan, and an external peer review was done.

Medical Center Corrective Actions:

We reviewed the RCA to determine whether the findings, conclusions, and recommendations were appropriate. RCA team members [redacted]

We requested further clarification regarding the placement of fire extinguishers. The facility risk manager stated that as of July 25, 2006, fire extinguishers have been in place in the operating rooms, and the staff has been trained regarding their use.

Allegation 2: A patient started to rouse during an emergency surgery because there was insufficient IV solution with anesthesia on hand.

Our review found that VAMC managers were aware of 2 cases that may be related to this allegation.

In the first case, a veteran became restless while undergoing an attempted mediport (a long term venous access catheter) placement. The veteran was receiving monitored anesthesia care (MAC). He became restless, and the procedure was abandoned. The veteran developed a 10% pneumothorax (collapsed lung) on his left side, but did not require any further intervention. The case was reported to the Surgical Case, Invasive Procedure, and Blood Utilization Review Committee.

The second case involved a 65- year -old veteran who underwent an emergency exploratory laparotomy without incident. The patient was transferred to the Intensive Care Unit immediately following the surgery, still receiving sedation and required ventilatory assistance. There was a slight delay in obtaining further

medications for sedation from the pharmacy, but without resultant harm to the patient.

Medical Center Corrective Actions:

In the first case, it was felt that the patient's restlessness was partly due to inadequate monitoring of oxygen saturation. The Chief of Surgery reviewed the case with the clinical providers and discussed opportunities for improvement.

In response to the second case, Pharmacy Service employees provided instruction to the nursing staff, so that should the future need arise, the necessary medications could be obtained and mixed in the ICU. A pharmacist would be available to provide the medications at the nursing staff's request, when they felt they could not mix the medications due to current patient care demands.

Although the VAMC was not aware of the particular case discussed in the complainant's allegation, the VA Medical center's corrective actions address the issues related to similar cases.

Allegation 3: Nursing staff have been withholding medications they feel are incorrect without consulting with a physician, then hiding the medications in a drawer.

The medical center had no reported incidents involving the purposeful withholding of medication. According to the medical center managers, nursing staff are expected to clarify provider orders based on their professional knowledge and judgment. Medical center managers provided us with documentation of medication error report logs, demonstrating a tracking method for possible medication misuse.

Medical Center Corrective Actions:

None indicated.

The VA Medical center's response addresses the issue raised by the complainant.

Allegation 4: A patient received the wrong medication. He was instructed to take it anyway. Instead, he turned it in at his next clinic appointment. When the prescription was returned to the pharmacy it was missing 3 tablets.

According to the medical center, the Chief of Police reported an allegation that 3 pills were missing from an outpatient's controlled substance medication prescription. The veteran received a prescription of Lorazepam (a prescription - only antianxiety medication) at the pharmacy window, and requested a different type of medication, specifically, Alprazolam (a prescription-only antianxiety

medication). The veteran admitted to taking some of his wife's Alprazolam, and claimed they worked better than the Lorazapam. The veteran was informed that only his doctor could change the prescription, and was instructed to ask his provider about changing prescriptions. The veteran did obtain a new prescription for Alprazolam, and left the bottle containing Lorazepam with the provider who had initially prescribed the Lorazepam. The bottle was later returned to the pharmacy by an LPN. After the bottle was returned to the pharmacy, it was noted by a pharmacist that 3 tablets were missing.

Medical Center Corrective Actions:

VAMC managers ordered an immediate inventory of Lorazepam tablets and the proper balance was on hand. The patient was contacted, and stated he never opened the Lorazepam bottle. The VA police were then contacted about the possible theft of the 3 tablets. When the VA police investigated the matter, it was found that in contradiction to his previous statement the patient had removed 3 tablets while enroute to his provider to get his prescription changed. Therefore there was no evidence that the medications had been pilfered by staff.

The VA Medical center's response addresses the issue raised by the complainant.

Allegation 5: Untrained staff monitors the narcotics vault. Reports are sanitized to eliminate discrepancies.

Medical center managers reported that they were not aware of any episodes of staff sanitizing monthly Controlled Substance Inspection reports. The medical center had undergone a Controlled Substance Accountability review during the Combined Assessment Program (CAP) review by the OIG in September 2005. It was recommended by the OIG that the medical center strengthen accountability controls over controlled substances with the following actions: (a) the Pharmacy Service staff perform annual wall to wall physical inventories of pharmaceuticals, (b) the responsibilities for ordering and receiving all pharmaceuticals are properly segregated, and (c) Pharmacy Service staff establish reorder points for the pharmaceutical inventories and input this information on the shelf labels.

Medical Center Corrective Actions:

Medical center managers concurred with the OIG findings and recommendations and took appropriate actions. These corrective actions included: performing wall to wall inspections of controlled substances, designating employees to order or to receive medications, delegating receipt of controlled substances to the pharmacy vault technician, and requiring an A&MM employee to verify receipt of controlled substance orders.

The medical center has an education and training program for Controlled Substance Inspectors, and has supporting documents, including the inspector worksheets and summary reports prepared for review by the medical center's leadership.

The VAMC took appropriate actions which respond to the issues raised by the complainant.

Allegation 6: Some patients in acute care have left the wards and/or the facility.

Medical center managers reported that they have a comprehensive reporting process which includes the reporting of missing patients. According to the medical center, if veterans occasionally leave the acute inpatient units without authorization and/or notification, upon return to the facility, the clinical provider will determine the veteran's disposition on a case by case basis.

Medical Center Corrective Actions:

The medical center's provided documentation of an RCA completed in response to five instances of missing patients, who's leaving the ward had the potential for but did not result in serious injury. As a result of the RCA, the following actions were taken to prevent these incidents from occurring: a revision to the Privileges Policy (a policy that refers to permission given to the patient to leave the unit for a specified period of time) with staff education reinforced, modifications to the Urgent Care Service with the placement of door sensors and panic alarms, and an increase in security presence.

The VA Medical center's response addresses the concerns raised in this allegation.

Conclusions:

Based on our evaluation of the VA Medical Center Director's review and corrective actions taken, and our review of the documentation provided to us, we concluded that the issues identified in the hotline complaint were appropriately addressed. We therefore will administratively close this hotline.

Nelson Miranda, Director
Washington, DC Region Office of Healthcare Inspections