

# Department of Veterans Affairs Office of Inspector General

# **Healthcare Inspection**

# Alleged Questionable Surgical Treatment at a VA Health Care System

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## **Executive Summary**

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to allegations concerning questionable surgical treatment provided by a specialty service surgeon (surgeon) at a VA Health Care System (the system). Specifically, the complainant alleged that:

- The surgeon's licenses had been suspended in two states prior to being employed at the system.
- The surgeon had several near misses with several related to wrong site surgeries.
- The Chief of Surgery declined to review the reported cases as sentinel events or take any action on [other] reported staff concerns.

We did not substantiate the allegation that the surgeon had suspended medical licenses in two states prior to being employed at the system. The surgeon's licenses from the two states were active and in compliance with VHA policy at the time the surgeon was hired. We did not substantiate the allegation that the surgeon had several "near misses." Only two alleged "near miss" cases were reported to us, both of which should have been referred to Quality Management staff and the Patient Safety Manager to determine if action was required. Neither of the two alleged "near misses" resulted in wrong site surgeries. We also identified one case with which we had concerns regarding the quality of surgical technique.

Although we substantiated the allegation that the Chief of Surgery declined to review the two alleged "near miss" cases as sentinel events, we concur that the cases did not meet the definition of a sentinel event.

We did not substantiate that the Chief of Surgery did not respond to staff's concerns regarding the surgeon's surgical techniques. The surgeon's privileges were suspended for 30 days and, among other requirements, the surgeon underwent proctoring before privileges could be reinstated. The proctor informed us that the surgeon used a surgical technique that "did not meet standard of care." We also found that the system did not delineate privileges for the surgeon, privileges were not facility or provider specific, and the system did not complete an initial FPPE on the surgeon as required.

We recommended that the system Director ensure that the two alleged "near misses" are referred to quality management staff to determine if action should have been taken, consult with Regional Counsel regarding possible clinical disclosure to the patient for whom quality of surgical technique concerns were identified, ensure that initial focused professional practice evaluations are completed on all newly hired providers, and ensure that privileges are facility and provider specific for all providers. The system Director accepted the surgeons "...resignation as a medical staff member at...VA Healthcare System and in the VA system..."

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. We will follow up on the planned actions until they are completed.



# DEPARTMENT OF VETERANS AFFAIRS Office of Inspector General Washington, DC 20420

TO: Director

**SUBJECT:** Healthcare Inspection – Alleged Questionable Surgical Treatment at a

VA Health Care System

#### **Purpose**

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant concerning the surgical treatment provided by a specialty service surgeon (surgeon) at a VA Health Care System (the system).

#### **Background**

The system has over 300 beds, and provides inpatient services for medicine, surgery, rehabilitation, mental health, and spinal cord injury. The system is affiliated with a University School of Medicine.

## **Allegations**

In July 2012, a complainant contacted OIG's Hotline Division and made allegations concerning the surgical treatment provided by a surgeon at the system. Specifically, the complainant alleged that:

- The surgeon had his licenses suspended in two states prior to being employed at the system.
- The surgeon had several near misses related to wrong site surgeries.
- The Chief of Surgery declined to review the reported cases as sentinel events or take any action on [other] reported staff concerns.

### **Scope and Methodology**

We conducted a site visit September 10–14, 2012. We interviewed the complainant, system leadership and quality management (QM) staff, staff physicians and registered nurses in the Surgical Services Department, the surgeon who was the subject of the complaint, and two specialty service surgeons consulted by the system. We reviewed relevant Veterans Health Administration (VHA) and system policies and procedures, credentialing and privileging profiles, committee minutes, QM documents, electronic health records (EHR) for two patients alleged to have had "near miss" surgical incidents, and one case with which we had concerns regarding the quality of surgical technique. We also reviewed twelve months of newly hired provider VetPro<sup>1</sup> profiles, patients' and external reviews from outside consultants, as well as information obtained from the two State Medical Boards where the surgeon allegedly had his licenses suspended.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

#### **Inspection Results**

#### **Issue 1: Medical Licensure Suspension**

We did not substantiate the allegation that a surgeon's medical licenses were suspended in two states prior to being employed at the system.

VHA policy states that applicants must possess at least one full, active, current, and unrestricted license that authorizes the licensee to practice in the state of licensure without any change being needed in the status of the license.<sup>2</sup> We found that the surgeon's licenses from the two states were active and in compliance with VHA policy<sup>3</sup> at the time the surgeon was hired.

#### **Issue 2: Near Misses Related to Wrong Site Surgeries**

We did not substantiate the allegation that the surgeon had several "near misses"; only two "near miss" cases were reported to us. Neither of the alleged "near miss" cases was associated with wrong site surgery. We determined that these two cases should have been referred to QM staff and the Patient Safety Manager to determine if action was required.

<sup>&</sup>lt;sup>1</sup> An internet enabled data bank for the credentialing of VHA health care providers that facilitates completion of a uniform, accurate, and complete credentials file.

<sup>&</sup>lt;sup>2</sup> VHA Handbook 1100.19, Credentialing and Privileging, November 14, 2008.

<sup>&</sup>lt;sup>3</sup> Ibid.

VHA policy states a close call is an event or situation that could have resulted in an adverse event, but did not, either by chance or through timely intervention. VHA policy also states that a close call is commonly referred to as a "near miss" incident. Near misses are opportunities for learning and afford the chance to develop preventive strategies and actions. They receive the same level of scrutiny as adverse events that result in actual injury. Near misses require reporting and documentation in WebSPOT. The system's local policy states that all adverse events, sentinel events, and near misses involving patients will be reported to the Patient Safety Manager in accordance with VHA policy.

Patient 1: We reviewed the EHR of a patient that was scheduled to have a procedure on the *right* side of the body. A history and physical dated May 31, 2012, indicated an initial impression of a procedure on the *left* side of the body. An Informed Consent dated June 1 at 4:43 a.m. indicated the procedure to be performed was on the *left* side of the body. A surgery attending note dated June 1 at 8:28 a.m. indicated that the imaging had been reviewed revealing that the planned procedure was mislabeled; it should "...be on the *right* side of the body". The note also indicated that the informed consent would be changed after discussing the error with the patient's family.

Patient 2: We reviewed the EHR of a patient that was scheduled for a *right* side surgery. The radiology report dated July 15, 2012, at 9:34 a.m. indicated findings on the *left* side of the body. Members of the surgical team independently reviewed the radiology reports and recognized the discrepancy. At 10:56 a.m., an addendum to the radiology report indicated that the procedure was on the *right* side of the body and that the original radiology report was mistakenly dictated indicating the procedure would be on the *left* side.

QM staff reported that they were unaware of either of these incidents and we did not find evidence of an incident report or other QM documents related to either case.

We substantiated the allegation that the Chief of Surgery declined to review the two above reported cases as sentinel events, because he did not consider these cases to rise to the level of sentinel events.

A sentinel event is an unexpected occurrence involving death, serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase "risk thereof" includes any process or variation for which a recurrence would carry a significant chance of serious adverse outcomes. We agreed

<sup>&</sup>lt;sup>4</sup> VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, March 4, 2011.

<sup>&</sup>lt;sup>5</sup> WebSPOT is the VHA Patient Safety Information System software application used for the purpose of reporting and documenting all adverse events.

<sup>&</sup>lt;sup>6</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>7</sup> Ibid.

with the Chief of Staff that the two above reported cases did not meet the definition of a sentinel event.

#### Issue 3: Chief of Surgery's Response to Reported Concerns

We did not substantiate that the Chief of Surgery did not respond to staff's concerns regarding the surgeon's surgical techniques.

We reviewed the EHR and reports of contact provided by operating room staff and the surgeon on a third patient that was scheduled to have surgery. The surgeon stated that he might use boiling water as a coagulant during the surgery, and requested a nurse to microwave water to boiling and bring it to the OR. The operating room staff informed the surgeon that microwaved fluids are not allowed in the OR and refused his request. Concerns regarding the surgeon's request and planned technique in this case were brought to the attention of the Chief of Surgery. The Chief of Surgery agreed that the staff acted appropriately by refusing the surgeon's request for boiling water.

Staff was also concerned the surgeon was using outdated surgical techniques, and that he seemed inexperienced with some of the surgical procedures he performed. Interviews with several staff as well as documents we reviewed indicated that the system leadership was aware of all three above cases as well as staff concerns regarding the surgeon's surgical abilities. Leadership suspended the surgeon's operative and minimally invasive procedure privileges for 30 days to investigate allegations of inappropriate behavior and concerns about competence in the operating room and the perioperative period. According to the letter reinstating the surgeon's privileges, the surgeon was required to:

- Meet with a psychologist to review communication style and develop strategies to improve communication with members of the operative team.
- Improve documentation in the EHR, specifically to complete an independent preoperative note detailing informed consent discussion, an attending surgical note within 24 hours of surgery, and a completed brief operative note immediately after surgery.
- Refer all patients with a potential new tumor diagnosis to the medical oncologist and Palliative Care Service preoperatively and to the tumor board prior to any elective operative intervention.
- Undergo 100 percent operative case review for the next 60 days.
- Attend a general specialty service surgery review course and a specialty service intensive care course within 120 days of reinstatement of privileges.
- Undergo proctoring by a specialty service surgeon selected by the Chief of Surgical Services and the Chief of Staff; the proctor's review will consist of

preoperative patient evaluations, indications for surgery, operative technique, and perioperative management in five operative cases.

All requirements for reinstatement with the exception of proctoring had been met at the time of our review. Although proctoring had occurred, only three of the required five surgical procedures were reviewed. In a letter to the Chief of Surgery, the proctor noted that the surgeon was "very slow", "his ...practice is not up to date", and his patients "could have been managed better".

We interviewed the proctor who described his observations while the surgeon performed a procedure. The proctor informed us that the surgeon did not follow usual surgical technique during the procedure. The proctor reported to us that "this practice did not meet standard of care."

#### Issue 4: Credentialing and Privileging

While not part of the complainant's allegations, in the course of our inspection we found that the system had two weaknesses in the credentialing and privileging program.

VHA policy requires that privileges are delineated.<sup>8</sup> Delineated clinical privileges are an accurate, detailed, and specific description of the scope and content of patient care services for which a practitioner is qualified; they are based on credentials and performance and are authorized by the facility. The delineation of privileges must be facility and provider specific. Privileges can only be granted within the scope of the medical facility mission and are based on the provider's experience and training.

The surgeon was granted full and active privileges to perform specialty service procedures including implantation of implantable devices. However, we did not find documentation of evidence that the surgeon had relevant training or experience, or current competence to perform selected procedures for which he was granted privileges.

VHA policy requires that a focused professional practice evaluation (FPPE) be completed to evaluate the privilege-specific competence of a provider who does not have documented evidence of competently performing the requested privileges of the system. Consideration for the FPPE is to occur at the time of initial appointment to the medical staff, or the granting of new, additional privileges. We did not find evidence that an initial FPPE had been initiated or completed on the surgeon.

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<sup>&</sup>lt;sup>8</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>9</sup> ibid.

#### **Conclusions**

We did not substantiate the allegation that the surgeon had suspended medical licenses in two states prior to being employed at the system. The surgeon's licenses from the two states were active and in compliance with VHA policy<sup>10</sup> at the time the surgeon was hired. We did not substantiate the allegation that the surgeon had several "near misses." Only two "near miss" cases were reported to us, both of which should have been referred to QM staff and the Patient Safety Manager to determine if action was required. Neither of the two alleged "near misses" resulted in wrong site surgeries. We also identified one case with concerns regarding the quality of surgical technique.

Although we substantiated the allegation that the Chief of Surgery declined to review the two alleged "near miss" cases as sentinel events, we concur that the cases did not meet the definition of a sentinel event.

We did not substantiate that the Chief of Surgery did not respond to staff's concerns regarding the surgeon's surgical techniques. The surgeon's privileges were suspended for 30 days and, among other requirements, the surgeon underwent proctoring before privileges could be re-instated. The proctor informed us that the surgeon used a surgical technique that "did not meet standard of care". We also found that the system did not delineate privileges for the surgeon, privileges were neither facility nor provider specific, and the system did not complete an initial FPPE on the surgeon as required.

The system Director accepted the surgeon's "...resignation as a medical staff member at ...VA Healthcare System and in the VA system..."

#### Recommendations

**Recommendation 1.** We recommended that the system Director ensure that the two alleged "near misses" are referred to quality management staff to determine if action should have been taken.

**Recommendation 2.** We recommended that the system Director consult with Regional Counsel regarding possible clinical disclosure to the patient for whom quality of surgical technique concerns were identified.

**Recommendation 3.** We recommended that the system Director ensure that initial focused professional practice evaluations are completed on all newly hired providers.

**Recommendation 4.** We recommended that the system Director ensure that privileges are facility and provider specific for all providers.

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<sup>&</sup>lt;sup>10</sup> VHA Handbook 1100.19.

#### **Comments**

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 8–11 for the Directors' comments.) We will follow up on the planned actions until they are completed.

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

John Vaidly M.

Healthcare Inspections

### **VISN Director Comments**

Department of Veterans Affairs

**Memorandum** 

**Date:** April 11, 2013

**From:** Director, VA Health Care Network

Subject: Healthcare Inspection – Alleged Questionable Surgical

Treatment at a VA Health Care System

**To:** Director, Healthcare Inspections (54)

**Thru:** Director, Management Review Service (10B5)

Thank you for the opportunity to review the subject report regarding the Healthcare Inspection at a VA Health Care System. I concur with the response submitted by the VA Health Care System. Please see Facility Director Comments for specific comments and actions.

# **Facility Director Comments**

Department of Veterans Affairs

**Memorandum** 

**Date:** April 11, 2013

**From:** Director, VA Health Care System

Subject: Healthcare Inspection - Alleged Questionable Surgical

Treatment at a VA Health Care System

**To:** Director, VA Health Care Network

The VA Health Care System has conducted a careful review of the subject report. I appreciate the comments and recommendations provided therein. The facility has reviewed the four recommendations in the report and provides the enclosed responses.

# Director's 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's report:

#### **OIG Recommendations**

**Recommendation 1.** We recommended that the system Director ensure that the two alleged "near misses" are referred to quality management staff to determine if action should have been taken.

Concur Target Completion Date: May 31, 2013

**Facility Response:** The two alleged near miss cases will be referred to quality management staff to determine if further action is required.

**Recommendation 2.** We recommended that the system Director consult with Regional Counsel regarding possible clinical disclosure to the patient for whom quality of surgical technique concerns were identified.

Concur Target Completion Date: May 31, 2013

**Facility Response:** A full case review and evaluation of the patient will be conducted. If concerns regarding quality of surgical technique are substantiated, the system Director will consult with Regional Counsel regarding possible clinical disclosure to the patient.

**Recommendation 3.** We recommended that the system Director ensure that initial focused professional practice evaluations are completed on all newly hired providers.

Concur Target Completion Date: September 30, 2013

**Facility Response:** Initial focused professional practice evaluations will continue to be completed on all newly hired providers in accordance with existing local policy and practice. The facility will review a sample of charts to provide documentation that this is occurring.

<b>Recommendation 4.</b> We recommended that the system Director ensure that privileges are facility and provider specific for all providers.		
Concur	<b>Target Completion Date: September 30, 2013</b>	
<b>Facility Response:</b> Privileges that are facility and provider specific will continue to be delineated for all providers in accordance with existing local policy and practice. The facility will review a sample of provider folders for documentation that this is occurring.		

## Appendix C

# **OIG Contact and Staff Acknowledgments**

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Glen Pickens, RN, BSN, MHSM, Project Leader Katrina Young, RN, BSN, MSHL, Team Leader Monika Gottlieb, MD Sandra Khan, RN

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