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Adm

admission

Department of Veterans Affairs
Office of Inspector General
Office of Healthcare Inspections

Personal issues are reviewed separately

The purpose of this white paper is to provide information regarding multiple complaints from a physician at the Western New York Healthcare System, Buffalo, NY. The system has two divisions, a tertiary care facility located in Buffalo, and a long-term care (LTC) facility located in Batavia.

August 21, 2008: 54BN received an anonymous hotline complaint from (b)(6). The complainant alleged that several veterans died because a surgeon, (b)(6) performed lung surgeries that he was not credentialed and privileged to perform. Additionally, the complainant alleged that (b)(6)'s "hygiene practices are not being met."

The complainant, who remained anonymous throughout the investigation, initially named three veterans: (b)(3):38 U.S.C. 5701, (b)(6) and (b)(3):38 U.S.C. Since we were unable to interview the complainant, we assumed that the allegation regarding "hygiene practices" referred to (b)(6)'s post-operative clean wound infection rate. During the inspection, we reviewed the provider's credentialing and privileging documents, mortality data, and wound infection rates. We reviewed the medical records of the three patients identified in the complaint and six other patients who expired after undergoing surgeries performed by the surgeon over an 18-month period of time. The system provided the names of the additional patients. We also reviewed VA Continuous Improvement in Cardiac Surgery Program (CICSP)¹ data and evaluated results of reviews of the provider's care conducted through the system's peer review process.

We concluded that the surgeon had appropriate credentials and privileges for the surgeries performed. We also concluded that when surgical procedures were necessary that the surgeon did not have privileges to perform, specifically lung procedures, a surgeon (b)(6) who was appropriately privileged either assisted with or performed those procedures. We also concluded that the surgeon followed established pre-operative prophylactic antibiotic protocols, appropriately consulted Infectious Disease clinicians, and had an excellent wound infection rate. We made no recommendations. This report (*Healthcare Inspection - Credentialing, Privileging and Infection Control Practices, VA Western New York Healthcare System, Buffalo, New York*) was published December 18, 2008, and is available on the OIG website.

May 6, 2009: 54BN received an e-mail from (b)(6) regarding a hotline alleging deficiencies in the surgery department at Batavia. This time the complainant

¹ CICSP data contains a comparative analysis of all the VA medical centers performing cardiac surgery.

identified herself as (b)(6) who worked as a (b)(6) at the (b)(6) division. We surmised (b)(6) was the anonymous complainant from the August 2008 hotline because the same patients were named in this complaint and a fourth, (b)(6) was added. (b)(6) was one of the additional six patients that the facility provided us during the August review, and we reviewed his medical record at that time. We mentioned to (b)(6) that Batavia had no surgery department so the complainant must be referring to Buffalo. According to (b)(6) also said she was being discriminated against, retaliated against as a whistle bower, and had filed EEO and whistle bower complaints. Since the four cases had already been reviewed, a decision was made not to take this hotline.

July 2, 2009: (b)(6) again contacted the IG alleging deficiencies in surgery, naming three additional patients ((b)(3):38 U.S.C. 5701, (b)(6) and (b)(3):38 U.S.C. 5701, (b)(6) and gave a synopsis of events as she perceived them. However this time the complainant did not just focus on one physician. She accused (b)(6) (b)(6) (b)(6) and a contract thoracic surgeon of poor quality of care and she accused (b)(6) (b)(6) of covering up errors that were made in the cases. She also accused a pathologist of covering up the true cause of death of a patient (b)(3):38 U.S.C. 5701. She named two surgeons who could back up her allegations: (b)(6) and (b)(6) (b)(6)

(b)(6) faxed (apparently from her home fax machine) a packet of information to Joe Vallowe after Joe telephoned her regarding her latest allegations. Included in the packet was medical record documentation for several patients and a response from the Office of Special Counsel, dated June 26, 2009. The OSC response showed that (b)(6) alleged a "violation of law, rule, or regulation, gross mismanagement, gross waste of funds, an abuse of authority, and a substantial and specific danger to public health and safety by employees..." at Buffalo. The OSC response also mentioned that (b)(6) criticized the December 2008 OIG report. OSC said that because OIG had conducted an investigation into the qualifications of (b)(6) OSC would take no further action. The OSC response stated that "we cannot find a substantial likelihood of a violation of law, rule, or regulation in the wording of the OIG's report. Thus, we will take no further action regarding these allegations." We believe (b)(6) and/or Joe have all documents from the various complaints that can be reviewed in detail.

54BN reviewed the medical records of the three additional patients.

(b)(3):38 U.S.C. 5701, (b)(6) was 70 years old in (b)(3):38 U.S.C. 5701, (b)(6) when he was diagnosed with a 7-cm mesenteric aneurysmal dilatation with dissection to his infrarenal distal aorta. His past medical history included thoracic aortic dissection with a stent graft in (b)(6) severe cardiomyopathy with non-reconstructible coronary artery disease, and chronic renal failure that was being treated with hemodialysis. He was evaluated by (b)(3):38 U.S.C. 5701, (b)(6) who recommended a 2-stage repair of the dissecting aortic aneurysm

using an endovascular approach. The infrarenal component was addressed successfully during a (b)(3):38 procedure and (b)(3):38 was scheduled for the second portion of his repair on (b)(3):38 U.S.C. 5

During the second procedure, (b)(3):38 U.S.C. 5701 (b)(6) placed a stent-graft into the aorta through an indwelling sheath via the axillary artery but had some difficulty advancing the graft. While attempting to withdraw the sheath with the graft, the stent deployed in the transverse aorta extending into the innominate artery. (b)(3):38 U.S.C. 5701 (b)(6) was unable to re-sheath the graft and called (b)(6) for assistance. (b)(6) came emergently to the OR but (b)(6) had some difficulty arresting the heart. He was eventually able to open the aorta and retrieve the stent.

(b)(6) alleged that the patient died within hours of this surgery. The medical record does not substantiate this. The medical record shows over the next several days and weeks, (b)(3):38 U.S. remained critically ill. He underwent another three procedures (2 abdominal operations and a tracheostomy). He developed multiorgan failure and coded on (b)(3):3. He could not be resuscitated. An autopsy performed on (b)(3):38 U.S.C. 5 identified the cause of death as sepsis with cryptococcal pneumonia, diffuse dissecting aortic aneurysm and a recent myocardial infarction.

(b)(3):38 U.S.C. 5701, (b)(6) was (b)(6) years old and living in the (b)(6). (b)(6) He had a long medical history that included diabetes, hypertension, coronary artery disease, hypokalemia, deep venous thrombosis, coronary artery bypass surgery, cerebrovascular accident with left hemiparesis, sleep apnea, peripheral vascular disease with heel ulcers, a right femoral-popliteal bypass in (b)(6) obesity, osteoarthritis, depression, chronic cystitis, dysphagia, presbyopia, anemia, history of tobacco and (b)(6) an dgastroesophageal disease.

A few weeks after his (b)(6) bypass surgery, his CLC physician (b)(6) noticed purulent drainage from the right inguinal incision and right heel ulcer as well as a large vesicular wound on the left heel. When (b)(3):38 returned to Buffalo for a follow-up appointment in the vascular clinic on (b)(6) the surgical resident, (b)(6) (b)(6) observed the same drainage. (b)(6) performed Versajet debridement to the right heel and gentle, probing debridement to the right groin. (b)(6) was concerned about a possible infection of the right inguinal graft and scheduled (b)(6) for operative debridement on the next day. She then arranged for (b)(6) to be admitted to the hospital that afternoon rather than returning to Batavia.

Two nurse aides and a driver had accompanied (b)(3):38 U.S.C. 5701, (b)(6) to the Buffalo facility with two other patients from the Batavia CLC. (b)(6) was transported via wheelchair to Buffalo admissions waiting area at some time after (b)(6) (time that he signed the consent form for the debridement in the surgical clinic). The nurse aides were aware that (b)(3):38 U.S.C. 5701, (b)(6) was going to be admitted. They reportedly confirmed his admission with an admissions clerk and left (b)(3):38 U.S.C. 5701, (b)(6) in the waiting room. The aides returned to Batavia with the other 2 patients.

About (b)(6) the admissions department called the ED to report that an unattended patient (b)(3):38 U.S.C. 5701, (b)(6) in the waiting area was bleeding and about to pass out. (b)(3):38 U.S.C. 5701, (b)(6) was transported in his wheelchair to the ED where he was found to be diaphoretic, cool and clammy. He had some bleeding from his right heel. His oxygenation was adequate after supplemental oxygen was started. The ED nurse obtained blood for laboratory tests and started IV Nitroglycerin. (b)(3):38 U.S.C. 5701, (b)(6) became more responsive. His blood pressure was 148/81 and his pulse was 126. At (b)(6) he became short of breath to the point of requiring intubation. At (b)(6) he coded and could not be resuscitated.

(b)(6) alleged that (b)(3):38 U.S.C. 5701, (b)(6) bled to death while unattended in the admissions waiting area. However, (b)(3):38 U.S.C. 5701, (b)(6) blood counts that were obtained shortly after arrival in the ED were 8.7/28.6 and he was responsive with a blood pressure and adequate oxygenation after initial treatment in the ED. An autopsy performed by (b)(6) (b)(6) on (b)(6) indicated that (b)(3):38 U.S.C. 5701, (b)(6) had suffered multiple pulmonary thromboemboli and had biventricular hypertrophy, ischemic cardiomyopathy, calcified valves and severe complicated arteriosclerosis of the aorta and major branches. (b)(6) listed the cause of death as pulmonary thromboemboli.

The facility discussed the events surrounding (b)(3):38 U.S.C. 5701, (b)(6) death with his (b)(6) and advised her of her rights to file for compensation as required. The facility also completed a root cause analysis (RCA) (b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

We found that based on the autopsy, (b)(3):38 U.S.C. 5701, (b)(6) died from pulmonary emboli, not an acute bleed. The facility conformed with the adverse event disclosure policy and addressed the problems that contributed to the above events.

(b)(3):38 U.S.C. 5701 was (b)(6) years old in (b)(6) and was living in the (b)(6) (b)(6). His past medical history included C5-C6 subluxation after a motor vehicle accident in August 2005 resulting in quadriplegia with multiple

complications related to the quadriplegia. He developed chronic, severe pain and spasticity that was treated with implantation of a medication pump containing clonidine, baclofen and morphine in (b)(6). He was scheduled for a pump refill at the Buffalo facility on (b)(6) but that appointment was cancelled and another appointment was made for (b)(6). On the eve of the (b)(6) appointment, (b)(3):38 U.S.C. 5701 complained of severe pain that was treated with PRN pain medications. He was still complaining of severe pain upon arrival at the Spinal Cord Clinic in Buffalo. The (b)(6) in the Spinal Cord Clinic sent (b)(3):38 U.S.C. 5701 for evaluation in the ED. According to the ED vital signs documented at (b)(6) (b)(3):38 U.S.C. 5701 temperature was 105.4.

(b)(6) came to the ED to refill the medication pump soon after (b)(3):38 U.S.C. 5701 arrived in the ED. According to (b)(6) 1004 procedure note, he interrogated the medication pump (it was empty) and reprogrammed the reservoir. He then refilled the pump with morphine, clonidine and baclofen. Because of the complaints of acute pain, (b)(6) set the pump to deliver a bolus of 5 mg of morphine over 60 minutes and gave (b)(3):38 U.S.C. 5701 50 mcg of IV baclofen and 2 mg of subcutaneous dilaudid.

According to the ED nurse's documentation, she gave (b)(3):38 U.S.C. 5701 2 mg IV ativan at (b)(3):38 U.S.C. 5701. At (b)(3):38 U.S.C. 5701 heart rate started to decrease and he arrested. (b)(3):38 U.S.C. 5701 was successfully resuscitated and taken immediately for a cardiac catheterization. He was found to have severely decreased cardiac function but no coronary artery disease. He was eventually diagnosed with sepsis. (b)(3):38 U.S.C. 5701 remained critically ill and ventilator dependent for weeks and months. He was nonresponsive and a consulting neurologist suspected a hypoxic-ischemic brain injury. During his prolonged hospital course, (b)(3):38 U.S.C. 5701 would have occasional temperature fluctuations that the infectious disease team suspected was related to dysautonomia. His condition continued to decline and he expired on (b)(6).

(b)(3):38 U.S.C. 5701 was (b)(6) patient at the CLC in Batavia. His temperature prior to leaving Batavia on (b)(6) was documented as 100.4. It is unclear when his temperature became significantly elevated. (b)(6) claimed that (b)(3):38 U.S.C. 5701 arrest on (b)(6) was related to medications administered by (b)(6) when he refilled the patient's medication pump. (b)(3):38 U.S.C. 5701 decompensated about 75 minutes after (b)(6) refilled the pump. However, (b)(3):38 U.S.C. 5701 temperature was very elevated when he arrived in the ED and he was subsequently diagnosed with sepsis and poor cardiac function. The records do not clearly identify a definitive reason for his cardiovascular collapse on (b)(6). The facility did not peer review this case as the patient died several months after the (b)(6) events and apparently did not suspect substandard care as a significant factor in his cardiovascular collapse.

Because we had concerns about the care in the ER, we asked Dr. Jerome Herbers to review the records in this case. He thought that documentation was limited and it would be difficult to make a definitive conclusion about the events in the ED on (b)(6). (Dr. Herbers further stated: "Based on the information I have, I would not fault the quality of care. At the same time, I could not say that everything was fine.")

(b)(6) also disclosed the names of five other patients: (b)(3):38 U.S.C. 5701
(b)(3):38 U.S.C. 5701 and (b)(3):38 U.S.C. She did not give the specifics of her concerns about (b)(3):38 U.S.C. to OHI but discussed him in her March/May 2009 complaint to OSC.

(b)(3):38 U.S.C. 5701 was a (b)(6) year old African American living in the (b)(6) in (b)(6). He had a history of dementia, seizures, a Billroth gastrectomy, prostate cancer and occasional behavioral issues. It appears that (b)(6) was concerned more about possible discrimination from the Batavia staff towards (b)(3):38 U.S.C. 5701 and other social issues than medical issues with this patient. (b)(3):38 U.S.C. 5701 was transferred from New York to Arizona in (b)(6) and eventually discharged from the VA facility in Arizona to live with his daughter. We could not identify any standard of care issues for (b)(3):38 U.S.C. 5701.

(b)(3):38 U.S.C. 5701 was (b)(6) year old man with dementia who was also living in the (b)(6) in (b)(6) under the care of (b)(6). (b)(3):38 U.S.C. 5701 developed mental status changes and lethargy on the morning of (b)(6). The nursing staff notified (b)(6) H who called (b)(3):38 U.S.C. 5701's wife. (b)(6) had initially wanted comfort care measures only but after conferring with (b)(6) on (b)(6), (b)(6) changed her mind and asked (b)(6) to transfer her husband to a medical facility. Per (b)(6)'s report of events of (b)(6) that she sent to Joe Vallowe, she was concerned that (b)(3):38 U.S.C. 5701's transfer was delayed because the Batavia staff distracted/confronted her about another patient while she was trying to make transfer arrangements for (b)(3):38 U.S.C. 5701. According to the available records, (b)(3):38 U.S.C. 5701 was transferred to a local hospital at (b)(6). At the local hospital, he was diagnosed with a right lung infiltrate and urinary tract infection, started on antibiotics, and transferred to the Buffalo VA facility. He arrived at Buffalo at (b)(6). He remained in Buffalo until (b)(6) when he was discharged to a non-VA nursing home where he died in (b)(6). We could not identify a significant problems caused by a possible delay in transfer from Batavia to the local hospital on (b)(6).

The last three patients identified by (b)(6) (b)(3):38 U.S.C. 5701 are patients who underwent procedures by a contract thoracic surgeon, (b)(6). Among other issues, (b)(6) alleged that (b)(6) does not provide adequate post-surgical follow-up to his VA patients.

(b)(3):38 U.S.C. 5701 was a (b)(6) year old man who was diagnosed with interstitial lung disease and scheduled for a video-assisted thoracic surgery (VATS) biopsy at Buffalo VA. (b)(6) performed the procedure on (b)(6) which was complicated by a liver laceration and diaphragmatic tear. The laceration and tear were repaired intraoperatively but after surgery, (b)(3):38 U.S.C. 5701 developed respiratory problems and had to be intubated for several days. He was eventually extubated, his respiratory

status improved, and he was discharged from the hospital on (b)(6). His case has been sent out for peer review.

(b)(3):38 U.S.C. 5701 was (b)(6) years old with a long medical history who transferred from Bath VA to Buffalo in (b)(6) with acute renal failure. He developed respiratory insufficiency of unknown etiology while in the Buffalo facility. (b)(6) performed an open lung biopsy on (b)(6) in an attempt to identify the cause of the respiratory problems. The biopsy was inconclusive. After a prolonged ICU and hospital stay, (b)(3):38 U.S.C. 5701 slowly improved and was discharged back to Bath on (b)(6). His case was not peer-reviewed.

(b)(3):38 U.S.C. was (b)(6) years old in (b)(6) when he developed a left pleural effusion. Analysis of the pleural fluid obtained by thoracentesis was indeterminate and (b)(3):38 was therefore scheduled for a VATS per (b)(6) on (b)(6). During the procedure, (b)(6) discovered a significant fibrous peel and decided to convert to an open procedure. While he was removing the fibrous peel, he was informed that fluid sent at the beginning of the procedure was positive for adenocarcinoma. (b)(6) decided to perform a left upper lobectomy and wedge resection. (b)(3):38 did well after surgery and was discharged home on July 1, 2009. His pathology showed a high grade pulmonary tumor that required adjuvant chemotherapy. Since July, he has had some problems with his heart rate but was able to attend his anticoagulation clinic (b)(6). This case has been referred for peer review but the results of the review are not yet available.

54BN conducted a scheduled CAP review of WNY HCS July 13-17, 2009. While we did not have the time to investigate all (b)(6) allegations, we did take the opportunity to review or re-review credentialing and privileging folders of (b)(6), (b)(6), (b)(6), (b)(6), and involved in the (b)(3):38 and (b)(3):38 cases, (b)(6), (b)(6), and involved in the (b)(3):38 case, (b)(3):38 U.S.C. 5701 (b)(6), and saw (b)(3):38 in the ED, and (b)(6) who had not done surgery in over 4 years but maintained surgical privileges). That review found that all the surgeons were appropriately credentialed and, with the exception of (b)(6) had appropriate privileges. We did find, however, that none of the physicians had the required on-going professional practice evaluations required by VHA Handbook 1100.19 for reprivileging. This resulted in a recommendation in the CAP report. This condition was also cited in the National Surgical Quality Improvement Program (NSQIP) review conducted November 3-4, 2008.

Additionally, we interviewed (b)(6) and (b)(6) (DUSHOM until 3 weeks prior to the CAP). We discussed the need to remove (b)(6) surgical privileges and the possible need to report (b)(6) to the NY State Licensing Board (NYSLB) because of falsifying medical records and failure to disclose her involvement in a tort claim. We also discussed personality/personnel issues. What came out of this discussion was that there is a sort of "us against

them" mentality/culture that has been allowed to take hold with (b)(6) (b)(6) (b)(6) and (b)(6) against (b)(6) (b)(6) and (b)(6). The following is a short synopsis of the personnel issues:

(b)(6) was dismissed from the system (b)(6) for falsifying her initial application (she failed to disclose being involved in a tort claim that resulted in a substantial payment) and for discrepancies in her LTC assessment documentation (back dating entries). She was removed from patient care service around (b)(6) while the system investigated the discrepancies in her medical record documentation and it was during this time that the failure to disclose the tort claim was discovered. Also, during this time she spent some time at the Buffalo campus. We were told that she was also (b)(6)

(b)(6) (b)(6) The COS staff said they were afraid not to hire her because they would be accused of discrimination. She is alleging that she is being discriminated against as (b)(6) and retaliated against for being a whistle blower.

(b)(6) (b)(6) and (b)(6) (b)(6) He was removed from his position at the affiliate medical school and came to VA as chief of surgery. This was arranged by a former COS. (b)(6)

(b)(6) (b)(6) However, he was removed from the chief of surgery position in (b)(6) (b)(6)

(b)(6) and was put into the position as (b)(6) a position he currently holds; and he is a member of the (b)(6). It is unclear why he was not required to do surgery or dismissed. He has not performed surgery since (b)(6) but has kept his surgical privileges. However, as of (b)(6) (b)(6) voluntarily resigned his surgical privileges. If he wants to resume those privileges, he will have to go through a formal mentoring program.

(b)(6) (b)(6) (highly skilled, we are told) was removed from patient care in (b)(6) pending an investigation of (b)(6) (b)(6) It was during this time that he apparently met (b)(6) and they began to share their perceptions of discrimination. The (b)(6) was substantiated but without intent. He was supposed to resume surgery, but at the time of the CAP review he had not performed surgery for 5 months. We were told by the COS that (b)(6) said (b)(6) was not giving him cases (b)(6) told the COS that (b)(6) refused to take cases. Apparently, (b)(6) has been sent back to work, but his contract is up in (b)(6). We were told that he and (b)(6) intensely

dislike each other, will not cover each other patients, and refuse to be in the same OR.

(b)(6) (b)(6) but wants a full-time position. He applied for (b)(6) but did not get it. We were told that because of this and because the system contracted with (b)(6) from the community to perform VATS procedures, which he wants to be privileged to do, he has cast his lot with the other three. All are alleging discrimination.

Of note, none of the above individuals approached any member of the CAP team during the week of the review.

The November 2008 NSQIP review and the CICSP review conducted February 25, 2009, (b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

The reports also (b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

OIG asked OMI to consider doing a review of the system's Surgical Service and 54BN briefed OMI on July 28. On August 13 via e-mail from Pat Christ, we were told that OMI declined the case. OMI reviewed patients cited in the complaints (unsure of the specific patients they reviewed) and did not concur with the complainant.

On July 7, the system sent four cases to (b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

for peer review. Three of the four cases were the same patients cited in the 2008 hotline complaint and reviewed by 54BN: (b)(3):38 U.S.C. 5701 and (b)(3):38 U.S.C. 5701

The fourth case, (b)(3):38 U.S.C. 5701 was one of six un-named patients that were also reviewed in 2008. The following is a (b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

(b)(3):38 U.S.C. 5705

In a telephone conversation with (b)(6) on (b)(6) said that (b)(6) contract most likely will not be renewed in (b)(6) which should alleviate the personality conflicts in cardiothoracic surgery. At the time of the CAP review (b)(6) the system had implemented the recommendation regarding pre-operative conference for all patients needing heart surgery, which responds to the (b)(3):38 U.S.C. 5705 (b)(6) also said during this conversation that the system was proceeding with reporting (b)(6) to NYSLB and that she has been on the radio accusing the system of being a racist organization.

In a separate telephone conversation with the (b)(6) on (b)(6) she stated that the system's ethicist has raised the question of HIPPA violations by (b)(6) because she sent medical records to a congressman (who we were told returned them to the system). Additionally, 51 has shown interest in (b)(5),(b)(7)(C) (b)(5),(b)(7)(C)

Conclusion: Based on the reviews of patient care by the OMI, (b)(6) and OHI, OHI cannot substantiate the multiple complaints of substandard patient care at the system. Clearly there are human resource issues that we believe the system is working to resolve, and possible HIPPA violation issues that may need further investigation by the system and/or 51. However, we recommend that OHI close the complaints regarding quality of patient care without further investigation.

Documentation for review in the *WNY HCS HL* folder on the Q drive:

(b)(3):38 U.S.C. 5705 (b)(3):38 U.S.C. 5 RCA, (b)(6)
(b)(3):38 U.S.C. 5705 ECMC
Action – (b)(6) E-mail – Intent to Report (b)(6)
Report Submitted by:

Katherine Owens, MSN

Kathy Gudgell, BSN, JD