



DEPARTMENT OF VETERANS AFFAIRS  
WASHINGTON DC 20420

January 11, 2016

The Honorable Carolyn N. Lerner  
Special Counsel  
U.S. Office of Special Counsel  
1730 M Street, NW, Suite 300  
Washington, DC 20036

RE: OSC File No. DI-15-3968

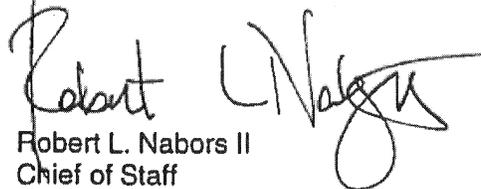
Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Evansville Health Care Center operated by the Marion Department of Veterans Affairs (VA) Medical Center, Marion, Illinois (hereafter, the Medical Center). The whistleblower alleged that an anesthesiologist failed to properly administer appropriate dosages of sedation medication to patients, instructed nurses to administer sedation, and that these practices constitute a violation of law and VA directives and represent a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as described in 5 United States Code § 1213(d)(5).

When this referral was received, the Under Secretary for Health was assigned to review this matter and prepare a report in compliance with section 1213. He, in turn, directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The report substantiates two of the five allegations. We found a violation of Veterans Health Administration policy. The report includes five recommendations to the Medical Center. We will send your office follow-up information describing actions that have been taken by the Medical Center to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,

  
Robert L. Nabors II  
Chief of Staff

Enclosure

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**DEPARTMENT OF VETERANS AFFAIRS  
Washington, DC**

**Report to the  
Office of Special Counsel  
OSC File Number DI-15-3968**

**Department of Veterans Affairs  
Evansville Health Care Center  
Evansville, Indiana**



**Report Date: December 2, 2015**

**TRIM 2015-D-5278**

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## Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Evansville Health Care Center (hereafter, the EHCC) operated by the Marion VA Medical Center, Marion, Illinois (hereafter, the Medical Center). Whistleblower a registered nurse (RN), who consented to the release of her name, alleged that an anesthesiologist failed to properly administer appropriate dosages of sedation medication to patients and instructed nurses to administer sedation, which may constitute violations of laws, rules, or regulations, and gross mismanagement, leading to a substantial and specific danger to public health. VA conducted a site visit to the Medical Center and EHCC on August 17–20, 2015.

### Specific Allegations of the Whistleblower

1. Between November 2014 and March 2015, Anesthesiologist failed to administer appropriate dosages of propofol to patients undergoing colonoscopies, causing those patients unnecessary pain and discomfort;
2. On March 4, 2015, Anesthesiologist prematurely discontinued the administration of sevoflurane to a patient undergoing a bunionectomy, resulting in the patient waking up during the procedure;
3. Anesthesiologist improperly instructed nursing staff to administer anesthesia medications;
4. Anesthesiologist has failed to properly store and dispose of anesthesia medications; and
5. Evansville VA management has not taken action to correct some of these problems.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

### Conclusions for Allegation 1

- VA **did not substantiate** that between November 2014 and March 2015, Anesthesiologist failed to administer appropriate dosages of propofol to patients undergoing colonoscopies, causing those patients unnecessary pain and discomfort. The evidence reviewed does not support that Anesthesiologist failed to adequately sedate his patients who were undergoing endoscopies at the EHCC.

- VA did not substantiate that [Anesthesiologist] responded to the patient's distress by slapping him on the chest. No documentation of record reports such an incident. This allegation appears to have been based solely on second-hand information, and aside from the whistleblower, was not corroborated by any other person we interviewed.

#### **Recommendations to the Medical Center**

1. Perform Ongoing Professional Performance Evaluations (OPPE) in accordance with Veterans Health Administration policy by having another anesthesiologist complete the evaluation of [Anesthesiologist].
1. Provide training for nursing and support staff regarding expectations for patients undergoing monitored anesthesia care versus general anesthesia, so that their understanding of sedation requirements, patient reaction, appearance, and responses to surgical/procedural stimulation is at a similar level.

#### **Conclusions for Allegation 2**

- VA did not substantiate that on March 4, 2015, [Anesthesiologist] prematurely discontinued the administration of sevoflurane to a patient undergoing a bunionectomy, resulting in the patient waking up during the procedure. Discontinuation of volatile anesthetic in the last few minutes prior to the end of surgery is not unreasonable or unusual. It is a common part of the continuum of "emergence" from anesthesia. VA did not find any evidence that [Anesthesiologist] failed to provide adequate anesthesia to this Veteran who underwent general anesthesia for podiatric surgery at the EHCC.
- VA did not substantiate that there were significant clinical issues regarding patient movement in this particular case.
- VA did not substantiate the allegation that the anesthesiologist refused to perform any surgical cases. VA found that when the anesthesiologist was not working in the operating room (OR), there simply were no surgeries or procedures scheduled.

#### **Recommendation to the Medical Center**

3. Consider creating a communication plan for local distribution that addresses and updates current coverage issues for the EHCC OR, including Anesthesia Service.

#### **Conclusions for Allegation 3**

- VA substantiated that [Anesthesiologist] requested licensed nursing staff to administer anesthesia medications; however, there was no evidence that this instruction was improper. The evidence suggests that the requests were infrequent and

necessitated only by emergent or otherwise similarly urgent clinical situations that arose during the clinical management of the case. In emergency situations in which the anesthesiologist is providing airway assistance to a patient, it is not uncommon to have other licensed staff administer medication in the presence of the anesthesiologist.

- Nursing and physician leadership did take appropriate action by investigating these instances and providing guidance to staff that this should not be a routine practice and should be limited to emergent-type situations where the anesthesiologist is present.

#### **Recommendation to the Medical Center**

4. Educate nursing staff regarding accepted circumstances when a RN may assist in the administration of anesthesia medication, i.e., emergency situations.

#### **Conclusions for Allegation 4**

- VA substantiated that ~~Anesthesiologist~~ has failed to properly store and dispose of anesthesia medications. The medication securement problem arose from issues with proper Pharmacy automated dispensing unit space for storage. However, these issues had been resolved prior to our arrival.
- VA did not substantiate that at any time these medications included Drug Enforcement Administration (DEA) Schedule II controlled medications, and VA found no pattern of irresponsibility.

#### **Recommendation to the Medical Center**

None.

#### **Conclusions for Allegation 5**

- VA did not substantiate that EHCC management has not taken action to address or correct any of the problems that were brought forward by the whistleblower. VA found that in each instance, the matter did receive investigative attention and that all levels of leadership took an active role in each instance.
- Despite the fact that the Associate Chief of Staff (ACoS) has direct authority only over the Administrative Officer at the EHCC and has no direct responsibility for operations at the EHCC, the ACoS is nonetheless seen by staff as the "Leader" of the EHCC due to his position there.

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### **Recommendations to the Medical Center**

5. Review the functional statement of the ACoS and consider the delegation of authority to the position at the EHCC to give inclusion and oversight to all of the functions and operations at the EHCC.

### **Summary Statement**

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule, or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the Office of General Counsel (OGC) has provided a legal review, VHA Human Resources (HR) has examined personnel issues to establish accountability, and the Office of Accountability Review (OAR) has reviewed the report and has or will address potential senior leadership accountability. VA found a violation VHA policy.

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## **I. Introduction**

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Evansville Health Care Center (hereafter, the EHCC) operated by the Marion VA Medical Center, Marion, Illinois (hereafter, the Medical Center). **Whistleblower**, a registered nurse (RN), who consented to the release of her name, alleged that an anesthesiologist failed to properly administer appropriate dosages of sedation medication to patients and instructed nurses to administer sedation, which may constitute violations of laws, rules or regulations, and gross mismanagement, leading to a substantial and specific danger to public health. VA conducted a site visit to the Medical Center and EHCC on August 17–20, 2015.

## **II. Facility Profile**

The Medical Center is part of Veterans Integrated Service Network (VISN) 15. This complexity level 2 facility serves Veterans across three states with the EHCC in Evansville, Indiana, and outpatient clinics in Carbondale, Harrisburg, Mt. Vernon, and Effingham, Illinois; Vincennes, Indiana; and Owensboro, Hanson, Mayfield, and Paducah, Kentucky.<sup>1</sup> A provider of services to beneficiaries of the Department of Defense Tricare program under the VISN 15 Tricare agreement, the Medical Center had over 40,000 unique patients and over 453,000 outpatient visits in fiscal year (FY) 2015. The EHCC had over 12,000 unique patients and over 88,000 outpatient visits in FY 2015; it provides 11 primary care services, 19 behavioral health services, and 21 specialty care services,

## **III. Specific Allegations of the Whistleblower**

1. Between November 2014 and March 2015, **Anesthesiologist** failed to administer appropriate dosages of propofol to patients undergoing colonoscopies, causing those patients unnecessary pain and discomfort;
2. On March 4, 2015, **Anesthesiologist** prematurely discontinued the administration of sevoflurane to a patient undergoing a bunionectomy, resulting in the patient waking up during the procedure;
3. **Anesthesiologists** improperly instructed nursing staff to administer anesthesia medications;
4. **Anesthesiologists** has failed to properly store and dispose of anesthesia medications; and
5. Evansville VA management has not taken action to correct some of these problems.

<sup>1</sup> Complexity Level 1A: complexity levels are determined by patient population (volume and complexity of care), complexity of clinical services offered, and education and research (number of residents, affiliated teaching programs, and research dollars). Complexity level 1 is the most complex and level 3 is the least complex; complexity for level 2 facilities is considered moderate. (VHA Executive Decision Memo (EDM), 2011 *Facility Complexity Level Model*).

#### IV. Conduct of Investigation

The VA team consisted of (b6) [REDACTED], Senior Medical Inspector, and (b6) [REDACTED], RN, Clinical Program Manager, both of OMI (b6) [REDACTED] M.D., Anesthesiologist, Chair, Anesthesia Field Advisory Committee; and (b6) [REDACTED], JD, MSHRM, HR Specialist representing OAR. VA reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured the EHCC's Operating Room (OR), Post Anesthesia Care Unit (PACU), and endoscopy suite, and we held entrance and exit briefings with Medical Center leadership.

VA initially interviewed the whistleblower via teleconference on August 6, 2015, and conducted a second interview with her on-site on August 18, 2015. VA also interviewed the following Medical Center and EHCC employees:

- (b6) [REDACTED] Associate Director of Patient Care Services (Nurse Executive)
- (b6) [REDACTED], Chief of Staff (CoS)
- (b6) [REDACTED], Acting Chief of Surgery
- (b6) [REDACTED] Associate, CoS (ACoS) and Acting Chief, Medicine
- (b6) [REDACTED] Gastroenterologist
- (b6) [REDACTED] Doctor of Podiatric Medicine (DPM)
- (b6) [REDACTED], Anesthesiologist
- (b6) [REDACTED], Certified Registered Nurse Anesthetist (CRNA)
- (b6) [REDACTED], CRNA
- (b6) [REDACTED], Acting Supervisor Credentialing
- (b6) [REDACTED], Chief, HR
- (b6) [REDACTED], Medical Support Assistant
- (b6) [REDACTED], Patient Safety Manager
- (b6) [REDACTED], Chief of Pharmacy
- (b6) [REDACTED], Pharmacy Technician
- (b6) [REDACTED], Quality Management Chief
- (b6) [REDACTED] OR Nurse Manager, Nurse Instructor, Conscious Sedation
- Employee 3 [REDACTED], RN, Assistant Chief of Nursing
- Employee 2 [REDACTED], RN, Nurse Manager
- (b6) [REDACTED] RN
- (b6) [REDACTED] RN
- (b6) [REDACTED], RN
- (b6) [REDACTED] RN
- (b6) [REDACTED], RN
- Employee 1 [REDACTED] RN
- (b6) [REDACTED]; RN
- (b6) [REDACTED] RN
- (b6) [REDACTED]; RN
- (b6) [REDACTED], RN

- (b) (6), Nurse Practitioner
- (b) (6), Surgical Technologist (ST)
- (b) (6), ST
- (b) (6), ST
- (b) (6), ST

## V. Findings, Conclusions, and Recommendations

### Background

Different types of facilities within the VA system have differing levels of complexity of anesthetic care with different models of anesthesiology practice. Some facilities have only anesthesiologists; some have anesthesiologists and nurse anesthetists working in care teams, and some have nurse anesthetists only. These providers may be assisted by nurse practitioners, biomedical technicians, anesthesiologist assistants (AA), physicians' assistants, RNs, or others as determined locally. Responsibility for care is determined locally; departmental policy rests with the Chief of Anesthesiology, or designee. A provider must meet the licensure requirements defined in his or her respective VHA qualification standards. His or her state license establishes the maximum scope of practice for each provider. VHA facilities, based on local needs, may specify privileges or scopes of practice that are narrower than those established by the state licenses.<sup>2</sup>

Moderate sedation can minimize a patient's pain and anxiety and is done routinely to increase the comfort of patients undergoing procedures and diagnostic treatments. The patient returns to an alert state for safe discharge more quickly from moderate sedation than from deeper forms of sedation. Persons ordering, administering, and supervising moderate sedation in support of patient care must be qualified and have appropriate credentials in addition to clinical privileges or scopes of practice.<sup>3</sup> Physicians, nurses and technicians work together in the clinical areas where sedation is practiced. An M.D. or CRNA functioning as an Licensed Independent Practitioner (LIP) administers the sedative medications. On September 23, 2014, the Medical Center received approval from the Interim USH to perform basic ambulatory surgery at EHCC. In the 9 months from the first case on November 14, 2014, to August 13, 2015, the facility conducted 150 such cases.

<sup>2</sup> VHA Handbook 1123, *Anesthesia Service*, March 7, 2007.

<sup>3</sup> VHA Directive 1073, *Moderate Sedation by Non-Anesthesia Providers*, December 30, 2014.

## Findings

### Allegation 1

Between November 2014 and March 2015, **Anesthesiologist** failed to administer appropriate dosages of propofol to patients undergoing colonoscopies, causing those patients unnecessary pain and discomfort.<sup>4,5</sup>

**Whistleblower** maintained that she regularly witnessed patients screaming and cursing in pain during colonoscopies; on one occasion a patient attempted to reach back to remove the scope from his rectum. Of all the staff interviewed, including the gastroenterology nurse and gastroenterologist, only one confirmed this, but admitted he had heard it second hand. No others corroborated this allegation. Many noted that nothing out of the ordinary had occurred with colonoscopies performed at the facility; they had practiced in other facilities prior to becoming employed at VA and attempts to remove scopes is common in both places. No other staff member recalled hearing patients screaming in pain.

According to **Whistleblower**, a patient became combative during the colonoscopy procedure in November 2014 because of the pain he was experiencing, and **Anesthesiologist** responded to the patient's distress by slapping him on the chest. **Anesthesiologist** said the purpose of what he classified as a firm push to restrain the patient was to calm him down to ensure his safety and to prevent him from falling off of the examination table. **Whistleblower** reported that the slap was hard enough to possibly harm the patient and not an appropriate method to soothe or calm a patient in pain.

VA spoke with members of the OR team. Two of them stated that during one procedure a patient did start to awaken and that **Whistleblower** placed his hand gently on the patient's chest, causing him to instantly lie back down. **Whistleblower** stated that she reported the slap to her chain of command. According to VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011, 4.d. Intentionally Unsafe Acts are defined as:

- (1) Intentionally unsafe acts, as they pertain to patients, are any events that result from:
  - (a) A criminal act,
  - (b) A purposefully unsafe act,

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<sup>4</sup> A colonoscopy is a test that allows a provider to look at the inner lining of the large intestine (rectum and colon) through a thin, flexible tube called a colonoscope. A colonoscopy helps find ulcers, polyps, tumors, and areas of inflammation or bleeding. During a colonoscopy, tissue samples may be collected (biopsy) and abnormal growths may also be taken out. During the test, patients may receive a pain medicine and a sedative put in a vein in the arm. These medicines help patients relax and feel sleepy during the test. <http://www.webmd.com/colorectal-cancer/colonoscopy-16695> ©2005-2015 WebMD, LLC.

<sup>5</sup> Propofol is the generic name for Diprivan, an intravenous medication for use in the induction and maintenance of anesthesia or sedation during certain surgeries, tests, or procedures. Propofol is only available as an injectable, and is only administered by specially trained healthcare professionals, (anesthesiologists, CRNAs, and nurses). Propofol was first approved by the Food and Drug Administration (FDA) in 1989. <http://www.drugs.com/pro/propofol.html> © 2000-2015 Drugs.com.

- (c) An act related to alcohol or substance abuse by an impaired provider and/or staff, or
- (d) Events involving alleged or suspected patient abuse of any kind.

Also, in paragraph 9 b. "Facility staff must report as per local policy, any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call to the Patient Safety Manager." VA found no evidence of any such incident being reported to leadership or to the Patient Safety Manager. In her interview, Whistleblower admitted she did not have any first-hand knowledge of this case due to her not having been in the room to witness the specific incident.

Whistleblower also asserted that the gastroenterologist had issues with sedation – specifically that patients undergoing procedures were inadequately sedated. When VA asked the gastroenterologist about making these allegations, she said she had not experienced any issues at all with the practice of the anesthesiologist, and that the level of sedation for her patients has always been appropriate. She went on to state that she also practices in the community and that patients often move during procedures, and at times, feel pain due to manipulation of the instrument through the colon. When she feels that patients need more anesthesia, she communicates this to the anesthesia provider to maximize patient comfort. The gastroenterologist reported being able to work closely with Whistleblower regarding the level of anesthesia to be used in each case and the timing within which a procedure is to be completed, so as to avoid a patient from being overly sedated at the point the procedure is completed and the patient is to be roused and taken to recovery. (She noted that such occurrences (which can endanger a patient's safety) do happen outside of the Medical Center).

One of the first procedures performed at the EHCC was slightly complicated due to the patient's medical condition. The patient underwent an endoscopy under a light level of anesthesia, resulting in the patient's tactile discomfort and verbal response. This case was successfully managed by Anesthesiologists. During VA's interview with the assistant OR nurse manager, we discussed the details about the allegation that Anesthesiologist failed to administer appropriate dosages of propofol to patients undergoing colonoscopies, causing them unnecessary pain and discomfort. The whistleblower was not present during this case, but she learned about the patient's experience through conversations with other Medical Center employees. Concerns about this case were reviewed by the Acting Chief, Surgery; no clinical issues were identified. Furthermore, the patient verbalized no recall of the procedure, nor expressed any unusual discomfort post-procedurally; this was not an unusual gastrointestinal (GI) case, especially given the patient's preoperative status and its relationship to her tolerance of sedation.

A recurrent theme in the interviews was that patients "moved a lot" during GI procedures; however, many interviewees were of the impression that Anesthesiologist patients moved more during their procedures than did the patients of other anesthesia providers. The general consensus from the practitioners with direct involvement with the subject cases was, however, that Anesthesiologists clinical management of his patients did not differ from that of other anesthesiologists.

The allegation of inadequate sedation was reported by [Whistleblower] to EHCC and Medical Center leadership, which included the Associate Chief of Nursing, ACoS and Acting Chief of Surgery. In response to the allegation, EHCC and Medical Center leadership completed a review of the case and interviewed all involved staff members. They concluded that there were no clinical care issues. During the site visit, VA interviewed all staff members involved in the case, along with those who had the opportunity to review [Anesthesiologists] cases; all said that there were no negative outcomes in any of his cases. During VA interviews specifically with staff members involved in [Anesthesiologists]' colonoscopy cases, none were aware of any reports of his patients complaining of being able to feel the scope during the procedure. In addition, leadership officials did not conclude that [Anesthesiologist] slapped a sedated patient who became combative during a procedure.

Based on our review of electronic health records (EHR) and information obtained from our interviews with leadership, we, the investigative team, found no documentation (or other recording) of the alleged events; nor could they be corroborated by other witness accounts.

In addition, we reviewed the anesthesia records of 30 of [Anesthesiologist]' patients, including the patients mentioned by the whistleblower and a patient who had a complaint about a procedure that was unrelated to pain. The evidence does not support that any of these patients had been inadequately sedated. During VA interviews with nursing staff members and through reviews of EHRs, we also learned that the post-anesthesia recovery room nurses routinely make post-procedure calls to all patients who have endoscopies and ask how their experience was; none reported concerns. During our review of the Patient Advocate's documents, VA did not find any patient complaints related to anesthesia services between June 1, 2014, and August 1, 2015.

As to supervisory monitoring of [Anesthesiologists]' professional performance, in accordance with VHA Directive 1100.19, *Credentialing and Privileging*, and VHA Directive 2010-025, *Peer Review for Quality Management*, and as a condition of opening the Ambulatory Surgery Center, OPPEs were and are completed on [Anesthesiologist]' practice every 6 months.<sup>6</sup> VA reviewed [Anesthesiologists]' Focused Professional Practice Evaluation (FPPE) and OPPE records and found no clinical issues; however, the reviews were completed by a surgeon instead of an anesthesiologist. For purposes of these reviews, a surgeon is not a peer of an anesthesiologist, based on the definition of a "peer" in VHA Directive 2010-025, *Peer Review for Quality Management*.

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<sup>6</sup> An FPPE or OPPE are considered Management Reviews. They are not protected by 38 U.S.C. § 5705. OPPE is the ongoing monitoring of privileged practitioners and providers to confirm the quality of care delivered and ensure patient safety. FPPE refers to an evaluation of privilege-specific competence of a practitioner or provider who does not have current documented evidence of competently performing requested privileges. FPPE occurs at the time of initial appointment and prior to granting new or additional privileges. FPPE may also be used when a question arises regarding a currently privileged practitioner or provider's ability to provide safe, high-quality patient care. Activities such as direct observation, clinical discussions, and clinical pertinence reviews, if documented, can be incorporated into this process. Information and data considered must be practitioner or provider specific, and could become part of the practitioner's provider profile analyzed in the facility's on-going monitoring. VHA Directive 2010-025, *Peer Review For Quality Management*, June 3, 2010.

## Conclusions for Allegation 1

- VA did not substantiate that between November 2014 and March 2015, **Anesthesiologist** failed to administer appropriate dosages of propofol to patients undergoing colonoscopies, causing those patients unnecessary pain and discomfort. The evidence reviewed does not support that **Anesthesiologist** failed to adequately sedate his patients who were undergoing endoscopies at the EHCC.
- VA did not substantiate that **Anesthesiologist** responded to the patient's distress by slapping him on the chest. No documentation of record reports such an incident. This allegation appears to have been based solely on second-hand information, and aside from the whistleblower, was not corroborated by any other person we interviewed.

## Recommendations to the Medical Center

2. Perform OPPEs in accordance with VHA policy by having another anesthesiologist complete the evaluation of **Anesthesiologist**.
3. Provide training for nursing and support staff regarding expectations for patients undergoing monitored anesthesia care versus general anesthesia, so that their understanding of sedation requirements, patient reaction, appearance, and responses to surgical/procedural stimulation is at a similar level.

## Allegation 2

On March 4, 2015, **Anesthesiologist** prematurely discontinued the administration of sevoflurane to a patient undergoing a bunionectomy, resulting in the patient waking up during the procedure.<sup>7</sup>

VA has established from record reviews and eyewitness accounts that the anesthesia was discontinued prior to the documented end of the procedure. There was likely a period of time during which the patient was under a suboptimal level of general anesthesia due to the low amount of anesthetic being delivered. This could have allowed the return of motor function (i.e., muscle movement) and primitive reflexes such as coughing. This, in itself, does not equate to inadequate anesthesia. In clinical practice, the timing of emerging a patient from anesthesia is part science, and part art, and is not always perfect.

While emerging from general anesthesia, the non-operative leg slipped from the OR table where it had been secured, and one or more of the OR staff responded in urgent

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<sup>7</sup> Sevoflurane is a nonflammable, nonexplosive liquid administered by vaporization and is a general inhalation anesthetic drug. It is used to induce and maintain general anesthesia in adult and pediatric patients for inpatient and outpatient surgery. <http://www.rxlist.com/ultane-drug.htm> Copyright © 2015 by RxList Inc. A bunionectomy generally involves an incision in the top or side of the big toe joint and the removal or realignment of soft tissue and bone. This is done to relieve pain and restore normal alignment to the joint. <http://www.webmd.com/skin-problems-and-treatments/bunion-surgery> ©2005-2015 WebMD, LLC.

fashion to secure it and restrain the patient while the surgeon completed closure of the incision. Staff involved reported that there had been 2–3 minutes between the patient's movement and the end of the procedure. They concurred that the patient had to be physically restrained, and there is evidence that the sterile boundaries were breached; however, there is no evidence that this resulted in the breach of the sterile operating field of the surgery.<sup>8</sup> The patient's record also indicates the patient suffered no adverse anesthetic or surgical outcome.

There was a related allegation that **Anesthesiologist** had mouthed “watch this” to the whistleblower prior to discontinuing the anesthetic agents, suggesting he intended to prematurely end the anesthetic and possibly cause an untoward event. No one else who was in the OR at that time validated this allegation. In interviews with other OR personnel, including the surgeon, there was concurrence that the anesthetic had ended prematurely and there was vague agreement regarding the timing between the patient's movements and when the surgery ended, being approximately 2–3 minutes. None of the other personnel who were there recall the patient's movement as having been a hindrance to completion of the procedure or posing a safety or sterility issue.

The podiatric surgeon did not recall any issues with the patient moving, other than recalling that the non-operative leg had to be restrained. The OR technicians similarly recalled the patient moved during the closure of the surgery; however, they could not recall that this had caused a break in the sterile field. They also did not confirm that **Anesthesiologist** mouthed or said anything untoward or inappropriate during the procedure. Their recall was that the integrity of the surgery was not compromised due to anesthetic being discontinued approximately 2-3 minutes before the surgery had been completed.

Our review of the anesthetic record found a 3-minute difference in timing between the discontinuation of the sevoflurane and the documented end of surgery, which is in keeping with recollection of these events by other OR staff.

In accordance with VHA policy, the Acting Chief of Surgery, requested a peer-review of the incident. A senior Medical Center CRNA completed the review. VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, states, “The term “peer reviewer” is defined as a health care professional who can make a fair and credible assessment of the actions taken by the provider relative to the episode of care under review. Factors to consider when selecting a peer reviewer include, but are not limited to, whether the individual has similar or more advanced education, training, experience, licensure, clinical privileges, or scope of practice.” The Medical Center did not violate VHA policy, or its own Medical Center Memorandum, 00-00QM-15-587, *Peer Review Program*, April 30, 2015, by appointing a senior CRNA, who also provides anesthesia

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<sup>8</sup> A sterile operative field is an isolated area where surgery is performed; it must be kept sterile by aseptic techniques. A sterile boundary is the location where the surgical drapes of the sterile operating field end. A sterile operative field is an isolated area where surgery is performed; it must be kept sterile by aseptic techniques. All of the equipment used to perform the operation is covered with sterile drapes and all personnel involved in the operation must be properly attired and gowned to maintain a sterile field.

care, to perform the peer review.<sup>9</sup> The peer review of this patient did not identify any clinical care issues.

In a postoperative follow-up on the patient, no evidence of infection of the surgical site or of trauma to the non-operative limb was found. The medical record contained no documentation of any adverse event due to patient movement, and the surgeon did not recall an issue with the anesthesia.

At the time of this incident the EHCC leadership instructed the staff members to review the facts surrounding the complaint, but failed to uncover any adverse or harmful events. These findings were reported to the VISN 15 Chief Medical Officer.

The whistleblower, [Whistleblower], also alleged that [Anesthesiologist] stated that, because of her verbal complaints against him, he would not do any surgical cases in early May. Based on our review of the EHCC OR's scheduling records, no physician procedures requiring the use of the OR (and hence anesthesia) had been scheduled in early May. This explains why the anesthesiologists had not been assigned cases during this period. Since there were no OR cases due to preauthorized, scheduled leave, the Chief of Surgery made an executive clinical decision to close the OR and to reassign OR staff.

A CRNA, who is assigned to the Medical Center, was asked to assist [Anesthesiologist] with sedation and other anesthesia procedures for a few days during the end of May 2015. Staff members we interviewed had positive reports about their experience and many felt [Anesthesiologist] functioned better in a team arrangement, to which he was accustomed from his experience in private practice.

During May 2015, the EHCC OR performed 15 cases and 3 endoscopy cases for a total of 18 cases. In June, EHCC performed 12 OR cases and 4 endoscopy cases for a total of 16, and in July they performed 6 OR cases and 5 endoscopy cases. Their workload is impacted by the number of part-time surgeons on staff, which currently adds up to 1.285 full time employee equivalents (FTEE).<sup>10</sup>

The approved leave report for EHCC in May 2015 showed 3 days where the OR was impacted by staff absence. In June, there were 15 such days and in July, there were 14. Of the 15 scheduled OR days in June, the OR was closed for 3 days due to the anesthesiologist being on approved leave to attend continuing medical education meetings. On the remaining 12 days, no cases had been scheduled, so there was no need for anesthesia services. In July, the OR was impacted for 12 days, 9 due to the anesthesiologist on approved annual leave (requested in April) and 1 because of approved sick leave. Also in July, the urologist was on unplanned extended medical leave for the entire month. During this time, according to the Associate Director of

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<sup>9</sup> Peer reviews for quality management are protected under 38 U.S. Code § 5705. Peer review, as described in this Directive, is intended to promote confidential and non-punitive processes that consistently contribute to quality management efforts at the individual provider level.

<sup>10</sup> Currently, 3 general surgeons serve to provide 1.0 FTEE; 2 ear, nose, and throat surgeons who serve as 0.08 FTEE; a urologist who serves as a 0.125 FTEE; a podiatrist who serves as a 0.03 FTEE; an orthopedic surgeon who serves as a 0.05 FTEE; and a gastroenterologist who serves as a 0.02 FTEE.

Patient Care Services (ADPCS) and Assistant Chief Nurse, several OR staff members were detailed to other areas within EHCC to cover staff shortages. With one anesthesia provider on-site, in accordance with VHA Directive 2011-037, *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center*, EHCC is restricted from performing cases that exceed the facility's capabilities, or which would occur outside of normal business hours. The first case of the day begins at 8:30 a.m., and the last case of the day must begin by 1:30 p.m. The anesthesia provider completes pre-anesthesia consultation evaluations daily from 2:00 to 4:30 p.m. On August 10, 2015, a 1.0 FTEE anesthesiologist transferred from another VA medical center to increase the number of anesthesiologists available, thereby increasing the number of ambulatory surgical procedures completed daily at EHCC.

## Conclusions for Allegation 2

- VA did not substantiate that on March 4, 2015, [Anesthesiologist] prematurely discontinued the administration of sevoflurane to a patient undergoing a bunionectomy, resulting in the patient waking up during the procedure. Discontinuation of volatile anesthetic in the last few minutes prior to the end of surgery is not unreasonable or unusual. It is a common part of the continuum of "emergence" from anesthesia. VA did not find any evidence that [Anesthesiologist] failed to provide adequate anesthesia to this Veteran who underwent general anesthesia for podiatric surgery at the EHCC.
- VA did not substantiate that there were significant clinical issues regarding patient movement in this particular case.
- VA did not substantiate the allegation that the anesthesiologist refused to perform any surgical cases. VA found that when the anesthesiologist was not working in the OR, there simply were no surgeries or procedures scheduled.

## Recommendations to the Medical Center

4. Consider creating a communication plan for local distribution that addresses and updates current coverage issues for the EHCC OR, including Anesthesia Service.

## Allegation 3

[Anesthesiologist] improperly instructed nursing staff to administer anesthesia medications.

The OSC referral letter to VA states that [Whistleblower] alleges that [Anesthesiologist] "directed [Whistleblower] to administer 7 cubic centimeters (cc) of succinylcholine to a patient during the week of April 20, 2015."<sup>11</sup>

<sup>11</sup> Succinylcholine chloride is indicated as an addition to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.  
<http://www.rxlist.com/anecline-drug/indications-dosage.htm>

The anesthesiologist was the sole provider of anesthesia at this time at the EHCC. No back-up to him was available in case of an emergency. In interviewing [Anesthesiologist], he admitted requesting assistance from nursing staff in administering medications during emergent situations. He stated he did not request such assistance in routine situations. During the interview, he provided an example of when he was initiating endotracheal intubation of a patient and the patient developed a laryngospasm. He had one hand on the patient's oxygen mask while the other was compressing the ventilation bag. He therefore required the assistance of a nurse to administer anesthetic medications to manage the laryngospasm<sup>12</sup> because he was unable to oxygenate the patient, manage the airway, and administer additional medications all at the same time.

In another case, this time in the endoscopy suite, he asked another nurse to administer propofol because he was actively trying to manage an airway using both hands and so needed an additional pair of hands to push the other medication. He stated that he typically pushes all anesthetic medications unless, like in that situation, he is using both hands to manage the airway. On May 12, 2015, the anesthesiologist sent an email to the National Anesthesia Office inquiring, "If a nurse can push medications under the direct supervision of the anesthesia provider?" On May 15, 2015, the Director, National Anesthesia Service replied, "Nurses should not be responsible for injecting medications as a routine. But in an extraordinary situation when the patient's condition demands it, this can be justifiable."

Two RNs interviewed stated they had pushed IV medications when the anesthesiologist requested them to do so. In both instances, the nurses said the anesthesiologist was engaged in active airway management. During the interview with one, she made gestures indicating that the anesthesiologist was bagging a patient. In the other, the RN stated the anesthesiologist was having technical issues with the anesthesia machine while also managing the airway. This particular case did involve the failure of the anesthesia machine: they were unable to administer anesthesia gas to the patient due to a failure of the ventilator. (This issue was reported to the biomedical department as well as the machine company and resolved).

In the absence of a functioning machine, [Anesthesiologist] did inform us that he made a decision to use propofol as the anesthetic, and in doing so, he asked the nurse to continuously administer the medication for the remainder of the case to keep the patient asleep, while he continued to focus on maintaining a proper airway. Both of the RNs did state they have previously run into similar circumstances in non-VA facilities and did assist anesthesia in a similar fashion in such occurrences. Even in her interview,

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<sup>12</sup> Laryngospasm happens when the muscles of the vocal cords seize up, restricting the flow of air into the lungs; temporarily making it difficult to speak or breathe. The onset of vocal cord spasms is usually sudden and once laryngospasm occurs, it leads to rapid oxygen decrease and subsequent organ dysfunction. If poorly managed, it has the potential to increase illness & death. Visanathan, T., Kluger, M.T., Webb, R.K., & Westhorpe, R.N., *Crisis management during anesthesia: laryngospasm*. *Quality & Safety in Health Care* 2005;14:e3 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1744026/pdf/v014p000e3.pdf>

**Whistleblower** stated that "**Anesthesiologist** was having trouble intubating a few days prior to April 27; he had me push succinylcholine."<sup>13</sup>

In both cases, both the ADPCS and the Assistant Chief of Nursing stated that they became aware of this issue and in response had informed staff not to administer any anesthesia medication unless required to do so in an emergency situation where a physician was nearby. The ADPCS also informed us that she also instructed Emergency Department nursing staff members not to administer anesthetic medications at the Medical Center either. The Chief of Surgery also discussed this case with the anesthesiologist and the Chief concluded that this was not a routine practice and had occurred during intubation of a patient.

### Conclusions for Allegation 3

- VA substantiated that **Anesthesiologist** requested licensed nursing staff to administer anesthesia medications; however, there was no evidence that this instruction was improper. The evidence suggests the requests were infrequent and necessitated only by emergent or otherwise similarly urgent clinical situations that arose during the clinical management of the case. In emergency situations in which the anesthesiologist is providing airway assistance to a patient, it is not uncommon to have other licensed staff administer medication in the presence of the anesthesiologist.
- Nursing and physician leadership did take appropriate action by investigating these instances and providing guidance to staff that this should not be a routine practice and should be limited to emergent-type situations where the anesthesiologist is present.

### Recommendation to the Medical Center

4. Educate nursing staff regarding accepted circumstances when an RN may assist in the administration of anesthesia medication, i.e., emergency situations.

### Allegation 4

**Anesthesiologist** has failed to properly store and dispose of anesthesia medications.

**Whistleblower** alleged that on numerous instances, the anesthesiologist left medication unattended in the OR until April 2015, including four 10 cc syringes of phenylephrine (a vasopressor), an unlabeled 10 cc syringe, and a vial of rocuronium (an intravenous muscle relaxant).

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<sup>13</sup> Intubation is the process of inserting a tube, called an endotracheal tube, through the mouth and then into the airway. This is done so that a patient can be placed on a ventilator to assist with breathing. The tube is then connected to a ventilator, which pushes air into the lungs to deliver a breath to the patient.  
<http://surgery.about.com/od/glossaryofsurgicallterms/q/Intubation.htm>

VA reviewed the circumstances related to this incident. The pharmacy technician assigned to the OR that day found medications on the Pyxis machine on February 24, 2015, at 3:55 p.m. during the machine's daily restocking: a vial of succinylcholine; a syringe with 1 milliliter of Robinul (a muscarinic anticholinergic used to reduce salivary and pharyngeal secretions); a syringe of propofol; and an empty syringe of Fentanyl. This issue was reviewed by nursing, pharmacy, and physician leadership. It was noted by the Chief of Pharmacy at the Medical Center that the pharmacy technician did find unsecured, unlabeled, non-controlled medications in the OR.<sup>14</sup> The EHCC pharmacy supervisor discussed this issue with the anesthesia provider, as well as with the Acting Chief of Surgery; it was later agreed to have pharmacy provide an appropriately-sized drawer within the automated dispensing unit in the OR for storage of anesthesia medications in between surgical procedures. After the storage unit was provided, there have been no repeat problems with unsecured, unlabeled medications.

The anesthesiologist admitted that this did occur. Having come from private practice where this was acceptable, he had been under the impression that the ORs were considered secure locations. According to a July 23, 2007, memorandum from the Deputy Under Secretary for Health for Operations and Management, a secure or controlled access OR is a measure that can be taken to "allow access to only authorized personnel, to ensure the security of unattended medications, anesthesia carts, or OR equipment and supplies." Also, in 2009, The Joint Commission acknowledged that current Federal regulations do not require the locking of an anesthesia cart containing non-controlled medications if it is in a secure area, such as the OR, and if all personnel are trained and authorized to be there as permitted by VHA Directive 2011-037, *Facility Infrastructure Requirements To Perform Invasive Procedures In An Ambulatory Surgery Center*, October 14, 2011.

#### **Conclusions for Allegation 4**

- VA substantiated that [redacted] has failed to properly store and dispose of anesthesia medications. The medication securement problem arose from issues with proper Pharmacy automated dispensing unit space for storage. However, these issues had been resolved prior to our arrival.
- VA did not substantiate that at any time these medications included DEA Schedule II controlled medications, and VA found no pattern of irresponsibility.

#### **Recommendation to the Medical Center**

None.

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<sup>14</sup> A non-controlled medication is one that is not under DEA supervision and control.

## **Allegation 5**

**Evansville VA management has not taken action to correct some of these problems.**

OSC's referral letter states that **Whistleblower** reported the alleged misconduct to her supervisors, **Employee 1**, Nurse Manager **Employee 2**, and Assistant Chief of Nursing **Employee 3**.

VA found that all leadership in **Whistleblower** chain of command addressed the issues she alleged with Nursing Service. In fact, her immediate supervisor communicated her concerns about the bunionectomy case to **Employee 2** and instructed her on how to report issues should she need to do so in the future. These issues were reviewed by the Patient Safety Manager, the Chief of Pharmacy, the Associate Chief Nurse, and the Chief of Surgery, and then forwarded for review to Senior Medical Center Leadership.

As part of this investigation, VA reviewed relevant documents and results of fact-finding activities conducted by the EHCC and Medical Center. We concluded that each issue had been appropriately managed by those responsible for reviewing and investigating each incident.

### **Local Leadership**

The ACoS also serves as Chief of Medicine for the Medical Center. VA noted that he has no direct authority over EHCC staff, with the exception of the Administrative Officer. It became apparent from our interviews that staff members at EHCC view the ACoS as the head of the EHCC.

As an example of the limited role of the ACoS at the EHCC, when investigating the allegation discussed above related to the alleged closure of the OR suite for 3 weeks in May, the ACoS stated he had no knowledge of that allegation or that the closure concerned some staff. (Again, we found the closure was justified, as discussed earlier in the report). When asked about the resolution of each of these issues, the ACoS had no information on the current status. He said that he was generally informed of the issues by email from the CoS, but that he is not typically included in the communication chain. The ACoS told us that he does make rounds in all areas within the EHCC and felt as though staff members were able to come to him with any concern.

### **Conclusions for Allegation 5**

- **VA did not substantiate that EHCC management has not taken action to address or correct any of the problems that were brought forward by the whistleblower. VA found that in each instance, the matter did receive investigative attention and that all levels of leadership took an active role in each instance.**
- **Despite the fact that the ACoS has direct authority only over the Administrative Officer at the EHCC and has no direct responsibility for operations at the EHCC, the**

ACoS is nonetheless seen by staff as the "Leader" of the EHCC due to his position there.

#### **Recommendation to the Medical Center**

5. Review the functional statement of the ACoS and consider the delegation of authority to the position at the EHCC to give inclusion and oversight to all of the functions and operations at the EHCC.

#### **VI. Summary Statement**

VA has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule, or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, OGC has provided a legal review, VHA HR has examined personnel issues to establish accountability, and OAR has reviewed the report and has or will address potential senior leadership accountability. VA found a violation of VHA policy.

## Attachment A

Documents in addition to the Electronic Medical Records reviewed:

Marion VA Medical Center (VAMC), *Anesthesia Reports*, October 2014 – July 2015.

Marion VAMC Medical Center Memorandum (MCM), 00-00QM-15-587, *Peer Review Program*, April 30, 2015.

Marion VAMC MCM, 11-112-14-095, *Delivery of Anesthesia Services*, October 31, 2014.

Marion VAMC MCM, 11-112-14-402, *Policy on Moderate (Conscious) Sedation for Areas Outside the Operating Room Suite*, October 31, 2014.

Marion VAMC MCM, 11-119-15-419, *The Intravenous (IV) Admixture Program*, May 7, 2015.

Marion VAMC Nursing Memorandum, 002-118-15-098, *Medication Administration*, March 16, 2015.

Marion VAMC Patient Advocate email, August 5, 2015.

Marion VAMC Pharmacy Memorandum, 45-0200, *Anesthesia-Controlled Substances Reconciliation in the OR*, August 2004.

Marion VAMC Pharmacy Memorandum, 50-0300, *Controlled Drugs-Auditing*, August 2005.

Marion VAMC Pharmacy Memorandum, 65-0100, *Automation-Pyxis Procedures*, August 2005, Revised February 2015.

Marion VAMC Physical Security Specialist email, August 18, 2015.

Marion VAMC Power Point Presentation, *Moderate Sedation*.

Marion VAMC – EHCC Nursing Service Standard Operating Procedure (SOP), NSP 14-AS-02, *Discharge Criteria Phase I to Phase II*, September 2, 2014.

Marion VAMC – EHCC Nursing Service SOP, NSP 14-AS-03, *Documentation in PACU-Phase I and II*, September 2, 2014.

Marion VAMC – EHCC Nursing Service SOP, NSP 14-AS-25, *Admission Criteria for PACU*, September 2, 2014.

Marion VAMC – EHCC Nursing Service SOP, NSP 14-AS-27, *Discharge Planning Guidelines*, September 2, 2014.

Marion VAMC – EHCC Nursing Service SOP, NSP 14-AS-28, *Discharge Criteria Phase II*, September 2, 2014.

Marion VAMC – EHCC Nursing Service SOP, NSP 14-AS-41, *Anesthesiologist/Surgeon Communication*, September 2, 2014.

Marion VAMC Patient Advocate email August 5, 2015.

VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

VHA Handbook 1004.08, *Disclosure Of Adverse Events To Patients*, October 2, 2012.

VHA Handbook 1907.01, *Health Information Management And Health Records*, March 19, 2015.

VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010.

VHA Directive 1073, *Moderate Sedation by Non-Anesthesia Providers*, December 30, 2014.

VHA Directive 2011-037, *Facility Infrastructure Requirements To Perform Invasive Procedures In An Ambulatory Surgery Center*, October 14, 2011.

VHA Directive 2012-026, *Sexual Assaults and Other Defined Public Safety Incidents in Veteran's Health Administration (VHA) Facilities*, September 27, 2012.

VHA Handbook 1050.01, *National Patient Safety Improvement Handbook*, March 4, 2011.

VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013.

VHA Handbook 1123, *Anesthesia Service*, March 7, 2007.

VHA Surgical Complexity listing of all VHA Facilities  
<https://vaww.nso1.med.va.gov/vasqip/DUSHOMEmbeddedPages/complexity.aspx>