DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

OCT 17 2011

In Reply Refer To:

Ms. Catherine McMullen Chief
Disclosure Unit
U.S. Office of Special Counsel
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505

RE: OSC File Nos. 01-10-3763 through 01-10-3772

Dear Ms. McMullen:

By e-mail dated August 18th, 2011, your office requested additional information related to the report in the above-subject matter. Please find enclosed the Department's response. Like the original report, it was prepared by the Office of the Medical Inspector, and it addresses the issues identified not only in the email request but also those raised during a phone conference with your staff on September 2, 2011.

Should you have any questions or concerns with the response, please contact Kathy Heaphy at 202-431-2789.

Sincerely yours,

Walter A. Hall
Assistant General Counsel

Enclosure

Subject: Addendum to OSC File Numbers DI-10-3763, DI-10-3764, DI-10-3765, DI-10-3767, DI-10-3768, DI-10-3769, DI-10-3770, DI-10-3771 and DI-10-3772 Report, Department of Veterans Affairs, Anesthesia Section, Washington, DC

1. This addendum clarifies questions raised by the Office of Special Counsel (OSC) regarding the subject report. Attached is a Table which includes an overview of the 8 cases addressed in this complaint.

2. OSC asked for clarification of the following:

A. The report stated that "[f]or each of the cases cited, staffing included both an anesthesiologist and a CRNA or SRNA present in the OR."

The whistleblowers informed OMI during interviews that each of these cases included staffing by an anesthesiologist and a CRNA or SRNA. The whistleblowers stated that although they were not originally assigned to these specific cases, they were available to volunteer to help each other.

As explained below, the patient anesthesia records completed by the whistleblowers during each case did not reliably include documentation of the times that the anesthesia providers entered and exited the operating room (OR). Therefore, OMI is unable to determine, from the anesthesia records, the duration of time that the additional anesthesia providers were present and/or assisting each other during any of these cases.

B. The whistleblowers maintained that no CRNA or SRNA was assigned to the cases on May 1, 2009, (case 3), and April 12, 2010, (case 5). In these cases, according to the whistleblowers, another anesthesiologist voluntarily assisted the provider without being assigned to do so for part of the procedures. Consequently, the whistleblowers alleged that the patients would have been at a greater risk of harm had there not been an unassigned volunteer. With respect to these two incidents, please identify the CRNA or SRNA who worked on these cases, whether these providers were assigned to assist or did so voluntarily without being assigned, and whether the absence of a second provider could have increased the risk of harm to the patients. If there was an increased risk of harm to the patients due to the absence of a second provider, please identify why management failed to assign a second provider, including the levels of difficulty of the cases the CRNAs and SRNAs were actually assigned to during the times of these cases.

Per the Anesthesia Section of Surgical Services, Policy 4-#1: Daily Operations, July 2010, Veterans Affairs Medical Center, Washington, DC, p. 1, "Because the environment of the OR is dynamic and the service needs of the Anesthesia Section are multiple and changing frequently, the clinical and administrative assignments must be fluid and modified as necessary throughout the day." The Medical Center does not maintain records of initial or interim anesthesia case assignments. Intraoperatively, anesthesia records are maintained by the anesthesiologist(s) and CRNA(s) of record, and provide the anesthesia provider's names who participate in the case. The anesthesia records completed by the whistleblowers did not reliably include documentation of the entrance and exit times, in and out of the OR, of the anesthesia providers. Therefore, OMI

is unable to determine, from the anesthesia record, the duration of time that the additional anesthesia providers assisted others in the OR.

Anesthesia training for physicians consists of one clinical year of general post-graduate medical training followed by three years of specialty training in clinical anesthesia. Successful completion of all specialty training requirements in anesthesiology, along with holding a current, permanent, unconditional and unrestricted license to practice medicine in at least one state or jurisdiction of the United States or province of Canada, are requirements for certification by the American Board of Anesthesiology (ABA). Additionally, the independent practice requirement conferred by the ABA dictates that all trained anesthesiologists "must be capable of performing independently the entire scope of practice in the specialty or subspecialty without accommodation or with reasonable accommodation."[1] All three whistleblower anesthesiologists are certified by the ABA and are expected to be capable of providing anesthesia care independently for all of the cases presented in this complaint. Moreover, the level of difficulty for these cases did not initially or at any time during the procedures necessitate the assistance of a second provider. These anesthesiologists, based on their training and experience, should have been able to independently provide safe and appropriate anesthesia care. It is without basis to suggest that the mere absence of a second provider, particularly mid- level practitioners or trainees, in these very routine cases may have increased the risk of harm to the patients. Absent any documented, demonstrated clinical need for the requested additional assistance in these cases, it can only be assumed that the requests for assistance were made for the convenience of the anesthesiologists in question. And the voluntary assistance, which by all accounts was readily available in each case, was rendered in a spirit of cooperation. Per the whistleblowers' own attestations to OMI regarding case 3 on May 1, 2009, there were two anesthesia providers involved in this case; however, the documentation in the patient's anesthesia record only mentions the anesthesiologist. Case 5 on April 12, 2010, had an anesthesiologist and a CRNA documented as participating in the care of the patient.

OMI did not find any evidence in the literature that it is safer for the patient for an anesthesiologist to be assisted by either a CRNA or SRNA. However, an article in *Anesthesiology* July 2000 titled, "Anesthesiologist Direction and Patient Outcomes," concludes that both 30-day mortality rate and mortality rate after complications (failure-to-rescue) were lower when anesthesiologists directed anesthesia care. The whistleblowers reported to OMI and it is documented in the anesthesia records that an anesthesiologist was assigned to all of the cases addressed in this report.[2]

Additionally, as stated above, the OMI is unable to accurately determine the involvement or duration of involvement of CRNAs and SRNAs in cases because the anesthesia records completed by the whistleblowers did not reliably include documentation of the entrance and exit times into the OR of additional anesthesia providers who provided assistance on the case.

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[1] The American Board of Anesthesiology, Inc. *Booklet of Information – Certification and Maintenance of Certification.* February 2011.

[2] Silber, Kennedy, Even-Shoshan, Chen, Koziol, Showan, Longnecker, *"Anesthesiologist Direction and Patient Outcomes."* Anesthesiology, V 93, No 1, Jul 2000, 152-165.

C. **Similarly, the whistleblowers alleged that a CRNA assisted an anesthesiologist on April 23, 2009, (case 2) even though she was not assigned to do so. Please confirm whether the CRNA was assigned to assist the anesthesiologist or did so voluntarily. Additionally, please identify whether the absence of a second provider on this case could have increased the risk of harm to the patient. If there was an increased risk of harm to the patient due to the absence of a second provider, please identify why management failed to assign a second provider, including the levels of difficulty of the cases the CRNAs and SRNAs were actually assigned to during the time of this case.**

As noted above, the independent practice requirement conferred by the ABA dictates that all trained anesthesiologists "must be capable of performing independently the entire scope of practice in the specialty or subspecialty without accommodation or with reasonable accommodation."[3] Therefore, as an independently licensed and privileged anesthesiologist, the assigned anesthesiologist is expected to and should be able to provide anesthesia for this case or any similar case.

As noted above, OMI did not find any evidence in the literature that it is safer for an anesthesiologist to be assisted by either a CRNA or SRNA. However, an *Anesthesiology* article from July 2000, "Anesthesiologist Direction and Patient Outcomes," concludes that both 30-day mortality rate and mortality rate after complications (failure-to-rescue) were lower when anesthesiologists directed anesthesia care. And as reported by the whistleblowers and documented in the anesthesia record, the Medical Center assigned an anesthesiologist in all of the cases addressed in this report.

Additionally, as stated above, the OMI is unable to accurately determine the involvement and duration of involvement of CRNAs and SRNAs in cases because the anesthesia records completed by the whistleblowers did not reliably include documentation of the entrance and exit times into the OR of all anesthesia staff.

D. **The statement above suggests that the anesthesia providers had the assistance of a CRNA or SRNA during the entire procedure. In the April 23, 2009, case (case 1), the whistleblowers alleged that an SRNA was permitted by the clinical coordinator anesthesiologist to assist for the initial few minutes of the case after she initially denied the request. With respect to this allegation, please identify how long the SRNA was permitted to assist the anesthesiologist as well as how long the anesthesiologist worked on this case without the assistance of a CRNA or SRNA. In addition, please identify whether any increased risk of harm existed to the patient due to the absence of a second provider during the portion of the case when the anesthesiologist worked unassisted. Please also identify the levels of difficulty of the cases the CRNAs and SRNAs were assigned to during the portion of time when the anesthesiologist worked unassisted on this patient.**

[3] The American Board of Anesthesiology, Inc. *Booklet of Information – Certification and Maintenance of Certification.* February 2011.

The anesthesia record, as documented by the anesthesiologist, does not indicate the specific periods of time the SRNA was present in the OR. Therefore, based upon this documentation, the OMI is unable to determine how long the SRNA was present.

A SRNA is a registered nurse enrolled in an accredited nurse anesthesia training program, e.g., a trainee, and not a privledged provider of anesthesia. Therefore, their participation in a case should be as a learner, to be educated, not as an assistant to a licensed, privileged provider. The SRNAs are not there to function as assistants. The absence of an assigned trainee should not have increased the risk of harm to the patient; in fact, it would allow the licensed provider more time to concentrate on the patient instead of teaching the trainee.

E. In the March 11, 2010, and September 17, 2010, cases, (cases 4 and 8, respectively); the whistleblowers alleged that the anesthesiologists were provided assistance by an SRNA. However, they alleged that due to the nature of the procedure or patient, a more experienced provider was needed. Please explain why the investigators believed the use of SRNAs was sufficient for these cases. In the March 11, 2010, case, (case 4), the whistleblowers alleged that an anesthesiologist assisted another anesthesiologist during most of the procedure even though she was not assigned to do so. Please verify that this assistance occurred and list the reasons why the agency believes that the additional anesthesiologist's assistance was not necessary. Please also identify the levels of difficulty of the cases the CRNAs were assigned to at the times of these cases.

The independent practice requirement conferred by the ABA dictates that all trained anesthesiologists "must be capable of performing independently the entire scope of practice in the specialty or subspecialty without accommodation or with reasonable accommodation." The assigned anesthesiologist is certified by the ABA and therefore should be capable of providing anesthesia care independently. The absence of a second provider should not have increased the risk of harm to the patients.

The OMI is unable to accurately determine the duration of involvement of SRNAs in either of these cases because the anesthesia records completed by the whistleblowers did not reliably include documentation of the entrance and exit times into the OR of anesthesia staff. Additionally, the OMI is unable to verify that an additional anesthesiologist assisted on case 4 because it is not documented in the anesthesia record.

The Veteran in case 4 became ill secondary to sepsis during the course of his admission. His ASA score during his initial evaluation was a 3 and reevaluated to a 5E just prior to his operation. While in the surgical intensive care unit (SICU) and before being transported to the OR, he was intubated, and started on medications to raise his blood pressure. In the OR, he required blood transfusions, and the whistleblower reported to the OMI that she left the room to pick up blood products at the blood bank, leaving the SRNA alone, as the only anesthesia provider in the OR. Postoperatively the record reflects there were "no anesthesia concerns observed. Stable on drips."

F. With respect to the two allegations from the April 14, 2010, cases, (cases 6 and 7); the whistleblowers alleged that a general anesthesiologist should not have been assigned to

these cases when cardiac anesthesiologists were available. Please explain why a general anesthesiologist was initially assigned to these cases.

Per VHA Handbook 1102.3, the expertise of a cardiothoracic anesthesiologist is required only for patients on cardiac bypass. A review of cases 6 and 7 indicates that neither case involved placing the Veteran on cardiac bypass. Therefore, any ABA certified anesthesiologist should be capable of providing anesthesia care independently on non bypass cases. The absence of a second provider should not have increased the risk of harm to these patients.

The anesthesia case complexity is noted on the attached Table. A summary, by ASA level, for the 8 cases follows. There is one case (case 7) with an ASA score of 2, five cases (cases 1, 2, 3, 5, 8) with ASA scores of 3, one case with an ASA score of 4T, and one case with an ASA score of 5E. Of the latter two more complex cases, the case 6 Veteran's airway was already controlled prior to coming to the OR and his surgical case, which took 53 minutes, was a sternal closure. And the case 4 Veteran, as noted above, was also already intubated prior to coming to the OR, was reported stable during the case and was actually left alone in the room with a SRNA by the anesthesiologist. All of these cases should be able to be managed by a board certified anesthesiologist.

The Medical Center always has at least two anesthesiologists, the clinical coordinator and the on-call physician, immediately available to help an anesthesia provider that needs assistance. Additional anesthesiologists, who are providing medical direction to CRNAs, could also be called upon in an emergency, if the patient in their room is stable. The whistleblowers' complaints of not having, or not being able to get assistance, are factually untrue. All whistleblowers were asked, during their interviews with the OMI, if there was ever a time when they needed assistance and were unable to get any assistance. All replied "no."

Attachment A

References

American Society of Anesthesiologists, Inc. (2008). Statement on documentation of anesthesia care, retrieved from www.asahq.org/For-Members-Standards-Guidelines-and-Statments.aspx.

Anesthesia Section of Surgical Services Policies (July 2010). Veterans Affairs Medical Center, Washington, DC.

Drolet, P. (2009). Management of the anticipated difficult airway—a systematic approach: continuing professional development. *Canadian Journal of Anesthesia, 56*, 683-701.

Levitan, R. & Ochrock, E. A. (2000). Airway management and direct laryngoscopy, a review and update. *Critical Care Clinics, 16*(3). Retrieved from http://www.medconsult.com.

The American Board of Anesthesia, Inc. (2011). *Booklet of Information*. Retrieved from http://www.theaba.org.

VHA Handbook 1102.3, August 23, 1999. *Criteria and Standards for Cardiac (Open Heart) Surgery Programs.*

VHA Directive 2010-018, May 6, 2010. *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures.*

Silber, Kennedy, Even-Shoshan, Chen, Koziol, Showan, Longnecker, *"Anesthesiologist Direction and Patient Outcomes."* Anesthesiology, V 93, No 1, Jul 2000, 152-165.

Attachment B
Table

Operation	ASA[4]	Mallampati Score & TMD or MH Distance	Pre-op Anesthesia Evaluation Findings	Type of Anesthesia	Post-op Anesthesia Report	Surgical Complexity[5] (from VHA Directive 2010-018) & Length of Procedure	Anesthesia Personnel
Case 1 Sex: M, Month & Year of Operation: April 2009, Age: 69, Wt. 196 lb, Hgt. 69 in, BMI=28							
Cholecystectomy (gall bladder removal)	3	Mallampati II "more than 3 FB"	Edentulous (no teeth) Prior tracheotomy Vital signs normal Neck full range of motion; history of tonsillar cancer and neck radiation	General anesthesia	"No anesthesia concerns observed"	General Surgery – Standard 3 hours, 33 minutes	1 Anesthesiologist (MD)
Case 2 Sex: M, Month & Year of Operation: April 2009, Age: 62, Wt. 282 lb, Hgt. 65 in, BMI=47							
Umbilical hernia repair	3	Mallampati III "more than 3 FB"	Neck full range of motion "obese" Mallampati II for 2007 thyroidectomy	General anesthesia	No post anesthesia note. Same day discharge. 1-day follow up RN note: "I'm doing fine."	General Surgery – Standard 34 minutes	1 Anesthesiologist (MD) 1 CRNA

[4] ASA Physical Status Classification System
ASA Physical Status 1 - A normal healthy patient
ASA Physical Status 2 - A patient with mild systemic disease
ASA Physical Status 3 - A patient with severe systemic disease
ASA Physical Status 4 - A patient with severe systemic disease that is a constant threat to life
ASA Physical Status 5 - A moribund patient who is not expected to survive without the operation
ASA Physical Status 6 - A declared brain-dead patient whose organs are being removed for donor purposes

[5] The Surgical Complexity Matrix is the assignment of each surgery procedure to an operative complexity designation of standard, intermediate, or complex.

Case 3 Sex: M, Month & Year of Operation: May 2009, Age: 61, Wt. 166 lb, Hgt. 61 in, BMI=24							
Right inguinal hernia repair	3	Mallampati II MH distance not noted	Neck range of motion normal Poor dentition Vital signs normal	Regional (Spinal done due to left lung upper lobe bullae)	No post anesthesia note. Same day discharge. No anesthesia concerns noted next day.	General Surgery – Standard 1 hour, 30 minutes	1 Anesthesiologist (MD)
Case 4 Sex: M, Month & Year of Operation: March 2010, Age: 69, Wt. 125 lb, Hgt. 68 in, BMI=18							
Debridement of left above-the-knee amputation	5E	Mallampati II MH distance not noted	Neck: Full range of motion The patient had a right internal jugular catheter inserted while in the SICU. His condition was guarded. External pacing and intubation done in the SICU, then transport to the OR.	General anesthesia	"No anesthesia concerns observed. Stable on drips."	Ortho – Standard 1 hour, 6 minutes	1 Anesthesiologist (MD) 1 SRNA
Case 5 Sex: M, Month & Year of Operation: April 2010, Age: 54, Wt. 214 lb, Hgt. 74 in, BMI=26							
Right lung video assisted thoracic surgery	3	Mallampati II "more than 3 FB"	Neck mobility within normal limits Full dentition Previous uncomplicated surgeries with General Anesthesia	General anesthesia	No anesthesia concerns observed.	Thoracic – Intermediate 3 hours, 27minutes	1 Anesthesiologist (MD) 1 CRNA

Case 6 Sex: M, Month & Year of Operation: April 2010, Age: 61, Wt. 304 lb, Hgt. 74 in, BMI=39							
Procedure: sternal closure Prior mitral value repair	4	Mallampati I "more than 3 FB"	Neck mobility within normal limits Full dentition	General anesthesia Arterial line Central line Pulmonary artery catheter	No anesthesia concerns observed. Vital signs stable. Intubated and sedated.	Thoracic – Intermediate 53 minutes	1 Anesthesiologist (MD) 1 CRNA
Case 7 Sex: F, Month & Year of Operation: April 2010, Age: 30 Wt. 158 lb, Hgt. 68 in, BMI=24							
Heller's myotomy (release of lower esophageal sphincter)	2	Mallampati I "more than 3 FB"	Neck mobility within normal limits	General anesthesia Arterial line	No anesthesia concerns observed.	General Surgery – Standard 2 hours, 22 minutes	1 Anesthesiologist (MD) 1 SRNA
Case 8 Sex: M, Month & Year of Operation: Sept 2010, Age: 77, Wt. 299 lb, Hgt. 70 in, BMI=43							
Colonoscopy, polyp removal	3	Mallampati II "more than 3 FB"	Neck mobility within normal limits	MAC: monitored anesthesia care	No post anesthesia note. Same day discharge. 1-day follow up RN note: "Okay. No problems."	General Surgery – Standard 1 hour, 13 minutes	1 Anesthesiologist (MD) 1 CRNA 1 SRNA