DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

FEB 25 2015

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-14- 1588

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Phoenix Department of Veterans Affairs (VA) Medical Center (hereafter, the Medical Center), Phoenix, Arizona. (b) (6) MD, alleged that the Medical Center engaged in conduct that may constitute a violation of law, rule or regulation, and 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 referenced in 5 United States Code § 1213(d)(5).

The Secretary asked that the Under Secretary for Health refer the whistleblower's allegations to the Office of the Medical Inspector, who coordinated a VA team that conducted a site visit to the Medical Center on November 3−5, 2014.

VA did not substantiate the whistleblower's three main allegations regarding supervision of surgical residents, surgeons practicing beyond the scope of their privileges, and illegal intrusions into the electronic health record of the whistleblower. While VA did substantiate that a physician had emailed the whistleblower suggesting (b) (6), that physician was acting appropriately in his role as Associate Program Director. VA made seven recommendations for the Medical Center and two recommendations for the Veterans Health Administration.

Findings from the current investigation are contained in the report, which I am submitting for your review.

Thank you for the opportunity to respond.

Sincerely,

Jose D. Riojas
Chief of Staff

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Report to the
Office of Special Counsel
OSC File Number DI-14-1588

Department of Veterans Affairs
Carl T. Hayden VA Medical Center
Phoenix, Arizona

Report Date: February 12, 2015

TRIM 2014-D-1454

Any information in this report that is the subject of the Privacy Act of 1974 and/or the Health Insurance Portability and Accountability Act of 1996 may only be disclosed as authorized by those statutes. Any unauthorized disclosure of confidential information is subject to the criminal penalty provisions of those statutes.

Executive Summary

At the request of the Secretary, the Under Secretary for Health (USH) directed the Office of the Medical Inspector (OMI) to assemble and lead a team to investigate complaints lodged with the Office of Special Counsel (OSC) by (b) (6), MD (hereafter, the whistleblower) a former employee at the Carl T. Hayden Department of Veterans Affairs (VA) Medical Center, Phoenix, Arizona, (hereafter the Medical Center). Dr. (b) (6) consented to the release of his name and alleged that the Medical Center engaged in actions that may constitute a violation of law, rule or regulation, and a substantial and specific danger to public health. He described issues regarding breaches in resident supervision, unqualified or untrained supervising physicians, and an impermissible intrusion into his privacy. A VA team conducted a site visit to the Medical Center on November 3–5, 2014.

Specific Allegations of the Whistleblower

1. **Physician residents were allowed to practice and perform surgery on patients without regard to their ability or competency, and were not properly supervised by senior practitioners resulting in serious patient complications and outcomes.**

2. **Supervising physicians performed and directed advanced laparoscopic surgical procedures which they were not qualified or trained to conduct or supervise, resulting in serious complications.**

3. **Beginning in March 2012, employees repeatedly accessed the whistleblower's medical records for unknown reasons and without cause constituting both an impermissible intrusion into his privacy and a violation of law and agency policy.**

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

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

Conclusions for Allegation # 1

- VA **did not substantiate** that residents performed surgeries without supervision, resulting in serious patient complications and outcomes.

- Resident supervision was evaluated using a number of parameters, and VA **did not substantiate** that residents performed major surgery in the Medical Center's operating rooms (OR) without supervision.

- VA did find that minor surgical procedures were sometimes performed by residents without the supervising attending in the room, as is appropriate with graduated levels of responsibility.

- There are no quality or safety issues identified in the National Surgery Office (NSO) Quarterly Reports for the Medical Center from 3rd quarter fiscal year (FY) 2013 to 3rd quarter FY 2014. The Medical Center was functioning at an acceptable level when compared with other VA medical centers of similar complexity and size.

- VA **did not substantiate** that records were falsified with regard to attending surgeon presence in the OR.

- VA did find that the OR nurses did not have a consistent way of documenting the attending and resident's level of participation in surgery.

- VA **did not substantiate** that surgical residents may have performed 30 to 40 percent of minor surgeries and 5 percent of major surgeries with no attending surgeon present, in violation of agency policies.

- VA found a minor problem with surgical attending notes and co-signatures, which were identified and addressed by the Medical Center.

- VA **substantiated** that Dr. (b) (6) in his role as Associate Program Director, had appropriately suggested to the whistleblower to (b) (6) to support the training requirements of graduated responsibility.

Recommendations to the Medical Center:

1. Develop a standard operating procedure (SOP) for nursing documentation of attending and resident participation in the OR in the Veterans Health Information Systems and Technology Architecture (VistA) Surgical Package, including the attendings' presence in the OR (as is currently being done), with specific attention to reporting accurately the attendings' and residents' role in the operation (operating versus assisting).

2. Until minor cases are moved to the new clinic procedure room, appropriately classify the procedures done in Room 2 as clinic procedures done in the OR.

3. Continue to conduct Resident Supervision Audits and document corrective actions as needed.

4. Educate all surgical attending staff on the role of graduated responsibility in surgical education, and continue to monitor for appropriate participation.

Conclusions for Allegations # 2

- VA **did not substantiate** that attending surgeons were performing procedures that they were not privileged to perform.

- Dr. (b) (6) and Dr. (b) (6) did perform a hand-assisted laparoscopic colon resection that developed a postoperative leak, which was identified and managed appropriately.

- The Medical Center's General Surgery privileging categories were based on organ systems and not on the technique used (open versus laparoscopic).

- VA **did not substantiate** that residents were allowed to perform surgery with inadequate supervision.

- Both the Chief of Surgery's and the other attending's recommendation to convert the (b) (6) 2013, Veteran's gallbladder surgery to an open procedure was appropriate in view of the technical difficulty of the case, the extended duration of the operation, and the risks associated with prolonged anesthesia.

- VA **did not substantiate** that the Veteran had not granted informed consent for conversion to an open procedure.

- VA **did not substantiate** that Dr. (b) (6) orders directly contravened the patient's wishes with regard to the type of surgery and constituted a violation of VA policy.

Recommendations to the Medical Center:

5. Revise the current list of clinical privileges in general surgery to include technique (i.e., open and/or laparoscopic).

6. Review Dr. (b) (6) colon leak rates against national standards.

Recommendation to VHA:

7. Develop a standardized template that facilities could utilize for their general surgery privileging forms, to ensure inclusion of technique (i.e., open and/or laparoscopic).

Conclusions for Allegation # 3

- VA **did not substantiate** that employees repeatedly accessed the whistleblower's medical records for unknown reasons and without cause constituting both an impermissible intrusion into his privacy and a violation of law and agency policy,

because all were authorized accesses in the performance of the employee's official duties.

- Although not a violation of law or policy, VA should consider alternatives for obtaining employee information (i.e., demographic) necessary for health care operations other than through accessing the VistA EHR.

Recommendation to the Medical Center

8. Explore and implement ethically sound practices to better protect employee privacy and engender trust in VA.

Recommendation to VHA

9. The Privacy Office and the National Center for Ethics in Health Care should review the policy related to accessing VistA EHR to obtain employee demographic information.

Summary Statement

VA has developed this report in consultation with other VA and VHA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, an abuse of authority, or was a risk to public health or safety. In particular, the Office of General Counsel (OGC) has provided a legal review and the Office of Accountability Review (OAR) has examined the issues from a Human Resources (HR) perspective, establishing individual accountability, when appropriate, for improper personnel practices. VA did not find any violations of law, rule or regulation, abuse of authority, or risk to public health and safety.

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I. Introduction

At the request of the Secretary, the USH directed OMI to assemble and lead a team to investigate complaints lodged with OSC by the whistleblower, a former employee at the Medical Center. The whistleblower alleged that the Medical Center engaged in actions that may constitute a violation of law, rule or regulation, and a substantial and specific danger to public health. He described issues regarding breaches in resident supervision, unqualified or untrained supervising physicians, and an impermissible intrusion into his privacy. A VA team conducted a site visit to the Medical Center on November 3–5, 2014.

II. Facility Profile

The Medical Center, part of Veterans Integrated Service Network (VISN) 18, is a complexity level 1c tertiary care facility with six community-based outpatient clinics in Phoenix, Mesa, Payson, Show Low, Globe, and Surprise, Arizona.[1] The Medical Center is a teaching hospital, providing a full range of patient care services, with state-of-the-art technology and research. It provides comprehensive health care through primary care, long-term care, and tertiary care in the areas of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, nutrition, geriatrics, and extended care. Comprised of 177 inpatient beds and 104 community living center beds, the Medical Center maintained an average daily census of 163, with 779,197 outpatient visits and 3,827 surgical procedures in FY 2013. The Medical Center runs eight main ORs per day; it uses six rooms for major cases, one room for cystoscopy, and one room for minor surgery. The minor surgery procedures (operations utilizing local anesthesia) are done in Room 2 for convenience, as the Medical Center currently does not have a clinic procedure room.

The Medical Center has 464 affiliation agreements with more than 145 institutions and supports and funds over 80 resident positions annually. It has fully integrated training programs with Banner Good Samaritan (family medicine, general surgery, oral maxillofacial surgery, internal medicine, obstetrics and gynecology, orthopedics, psychiatry, cardiology, endocrinology, gastroenterology, geriatrics, and pulmonary/critical care medicine), Maricopa Integrated Health System (psychiatry and radiology), and the Mayo School of Graduate Medical Education (dermatology, otolaryngology, and gastroenterology). The Medical Center also has an active affiliation with the University of Arizona College of Medicine–Phoenix, and is involved in the educational programs of A.T. Still University and the Midwestern College of Osteopathic Medicine. It has nursing affiliations with Arizona State University, University of Phoenix, Grand Canyon University, Chamberlain College, Northland Pioneer College, and the Maricopa Community Colleges.

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[1] Complexity level 1c: 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. (Veterans' Health Administration Executive Decision Memo (EDM), *2011 Facility Complexity Level Model).*

III. Specific Allegations of the Whistleblower

1. **Physician residents were allowed to practice and perform surgery on patients without regard to their ability or competency, and were not properly supervised by senior practitioners resulting in serious patient complications and outcomes.**

2. **Supervising physicians performed and directed advanced laparoscopic surgical procedures which they were not qualified or trained to conduct or supervise, resulting in serious complications.**

3. **Beginning in March 2012, employees repeatedly accessed the whistleblower's medical records for unknown reasons and without cause constituting both an impermissible intrusion into his privacy and a violation of law and agency policy.**

IV. Conduct of Investigation

The VA team consisted of (b) (6), MD, Interim Director, OMI; (b) (6) (b) (6), MD, Deputy Medical Inspector; (b) (6), RN, Clinical Program Manager; (b) (6) MD, Chief Surgical Consultant, VISN 17; and (b) (6) HR Specialist from Office of Accountability Review. In addition, also consulting on the investigation, (b) (6), VHA Privacy Office Manager; (b) (6), Director, Information, Access, and Privacy Office; and (b) (6), Health Care Ethicist, National Center for Ethics in Health Care.

On June 6, 2014, we interviewed the whistleblower to gather specific details of his allegations. The team initially conducted the entrance briefing on June 16, but was called back to Washington, DC, to avoid interference with the visits of the Office of the Inspector General and Federal Bureau of Investigation, occurring at the Medical Center at that time.

On October 29, the VA team again interviewed the whistleblower by phone and conducted a subsequent face-to-face interview with him on November 3, the first day of the site visit, at the VISN 18 office in Gilbert, Arizona. The team reviewed policies, additional reports, memorandums, and other relevant documents listed in Attachment A.

On November 4, VA held an entrance briefing and discussed the Department's whistleblower protection policy with Medical Center leadership:

- (b) (6) Interim Medical Center Director
- (b) (6), DO, Chief of Staff
- (b) (6), Acting Associate Director
- (b) (6), Deputy Chief of Staff
- (b) (6), Assistant Director
- (b) (6), Quality Manager

Participating by teleconference:

- (b) (6), Acting Director, VISN 18
- (b) (6), Chief Medical Officer
- (b) (6), Deputy Director, VISN 18

The team conducted multiple interviews with:

- (b) (6), MD, the whistleblower
- (b) (6), Information Security Officer
- , HR Specialist Credentialing and Privileging (C&P)
- , Chief of VA Police
- , DO, Chief of Staff
- , Administrative Assistant to the Chief of Staff
- , HR, Employee Labor Relations
- , MD, staff surgeon
- , MD, former Chief of Surgery
- , MD, Chief of Vascular Surgery
- , MD, Acting Chief of Surgery
- , MD, staff surgeon
- , Nurse Manager, OR
- , RN, staff nurse, OR
- , RN, staff nurse, OR
- , RN, staff nurse, OR
- , MD, Program Director, Phoenix Integrated Surgical Residency, Banner Good Samaritan Hospital
- , MD, surgical resident
- , MD, surgical resident
- , MD, surgical resident
- , MD, surgical resident
- , MD, surgical resident
- , DO, orthopedic resident (general surgery intern)
- , MD, surgical resident
- , Privacy Officer
- , Privacy Officer
- , MD, VISN 18

On November 5, 2014, VA held an exit briefing with the Medical Center Leadership:

- (6), Associate Director and Acting Medical Center Director
- (b) (6), DO, Chief of Staff
- (b) (6), Deputy Chief of Staff
- (b) (6), Assistant Director
- (b) (6), Quality Manager

Participating by teleconference:

- (b) (6) VISN 18 Acting Director
- (b) (6), VISN 18 Chief Medical Officer
- (b) (6), VISN 18 Deputy Director

V. Findings, Conclusions, and Recommendations

Allegation #1

Physician residents were allowed to practice and perform surgery on patients without regard to their ability or competency, and were not properly supervised by senior practitioners resulting in serious patient complications and outcomes.

1a. The whistleblower observed numerous instances where there were no supervising practitioners present for surgeries conducted by residents. The whistleblower reviewed surgical logs detailing physician attendance during the procedure and discovered that in many instances the record of the procedure stated that a supervising physician was physically present for the surgery, when in reality it was performed by an unsupervised resident. Records were falsified to conform to agency regulations requiring supervisor physicians in all non-emergency surgical situations. Thirty to 40 percent of minor surgeries and 5 percent of major surgeries were performed by unsupervised residents, with no attending present, in violation of agency policies.

Findings

The Medical Center's OR suite consists of seven main operating rooms. The general surgery staff uses three of them: two major surgery rooms and one minor procedure room, Room 2. The Medical Center does not have a clinic procedure room, so for convenience they use Room 2 in the OR for minor procedures such as skin biopsies, suturing, or removal of small lesions, requiring only local or topical anesthesia. There is no conscious sedation or general anesthesia done in OR Room 2. The Medical Center is in the process of building a clinic procedure room.

The Accreditation Council for Graduate Medical Education (ACGME) provides the following guidance regarding resident physician supervision: [2]

VI.D.2.: Supervision of Residents: "The program must demonstrate that the appropriate level of supervision is in place for all residents who care for patients. Supervision may be exercised through a variety of methods. Some activities require the physical presence of the supervising faculty member. For many aspects of patient care, the supervising physician may be a more advanced resident or fellow. Other portions of care provided by the resident can be adequately supervised by the immediate

[2] http://www.acgme.org/acgmewb/Portals/0/PDF/Common_Program_requirements_07012011[2].pdf.

availability of the supervising faculty member or resident physician, either in the institution, or by means of telephonic and/or electronic modalities. In some circumstances, supervision may include post-hoc review of resident-delivered care with feedback as to the appropriateness of that care."

VI.D.4.: Supervision of Residents states: "The privilege of progressive authority and responsibility, conditional independence, and a supervisory role in patient care delegated to each resident must be assigned by the program director and faculty members."

In ACGME "Frequently Asked Questions," effective July 1, 2011, updated June 18, 2014, ACGME provides additional guidance about resident supervision. "Residents enter programs as novices and are expected to graduate as accomplished physicians capable of functioning competently and without supervision.....Great care must be taken in determining the level of involvement each resident will have in direct patient care so as to ensure patient safety. Another level of advancement lies in the granting of supervisory authority to a resident over a more junior resident. This will require not only documentation of medical knowledge and procedural competency skill sets, but also documented ability to effectively teach and oversee the work of others. At any level of assignment, the initial few days or weeks should be carefully monitored to ensure that the individual resident is capable of functioning in his/her assigned role. If not, then remediation will be necessary before the assignment can continue." The Phoenix Integrated Surgical Residency has graduated levels of responsibility from postgraduate year (PGY) -1 through PGY-5.[3]

According to the Medical Center's policy on surgical resident supervision, the attending must be present in the surgical room before, beginning, and throughout major operative cases. "The exception will be if routine, low risk procedures such as skin biopsy or suturing done in the OR for convenience," under these circumstances, "the supervisory practitioner is identified in the documentation by the resident." The attending is required to evaluate all patients and write a pre-procedure note describing the findings, diagnosis, plan for treatment, and choice of specific procedure to be performed.

VA interviewed the Residency Program Director, three supervising physicians (attendings), the Chief of Vascular Surgery, the former and current Chief of Surgery, seven surgery residents in PGY 2 to 5 (of which five were selected by the whistleblower), the OR Nurse Manager, and three OR staff nurses regarding the presence of attending surgeons in the OR during surgery.

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[3] **PGY** refers to a North American numerical scheme denoting the progress of post-graduate dental, medicine, medical physics, or pharmacy residents in their residency program. It is used to stratify responsibility in most training programs and to determine salary. The grade of the resident is denoted with a numeral after the PGY designation, such as PGY-3 for a third year resident. The length of residency depends mostly on the field a graduate chooses to take. Medical specialties such as family medicine and internal medicine often require only three years, whereas surgery usually requires a minimum of five, and neurological surgery is the longest at seven years. http://en.wikipedia.org/wiki/PGY .

All residents stated that the attending routinely evaluates and writes the pre-procedure note on their assigned patients for major and minor cases. All interviewees, except the whistleblower, stated that the residents were not allowed to perform major surgery without the attending surgeons in the room. The OR nurses said that they do not allow the residents to bring patients back into an OR room without the presence of an attending, and if a resident brought in a patient without the attending, the nurse would immediately call the attending or the Chief of Surgery.

The surgical residents, attendings, and the OR nurses did report variable attending participation in Room 2, commensurate with the attending's assessment of the resident's competence, and the complexity of the minor procedure. The nurses reported that they would never start a case in Room 2 without confirming the attending of record and his availability. All of the residents said that, while at times the attendings are not physically present (not providing direct supervision) during minor procedures in Room 2, they discuss the surgical plan with the attending surgeon immediately before each procedure, and that attendings are immediately available, if needed. No one could give an example when help was needed and was not available.

All of the general surgery residents stated that the level of resident supervision at the Medical Center was equal to, or greater than, that of other non-VA hospitals where they had received their training. The orthopedic resident, who rotated on general surgery as an intern, reported that at one non-VA hospital he was more closely observed when caring for private patients, but supervision was about the same for other patients. All residents said that they were not aware of any complications or poor patient outcomes due to the actions of a resident operating without direct supervision.

VHA Handbook 1102.01 January 30, 2013, notes that the NSO is responsible for operational oversight and policy related to the VHA surgical programs, including surgical outcomes data production and analysis, and associated data stewardship. The NSO collects and monitors quarterly reports of Medical Center data. VA reviewed the FY 2013 and first 3 quarters of FY 2014 NSO Quarterly Reports, 2 years of Surgical Service meeting minutes, 2 years of Morbidity and Mortality (M&M) Conference records, 2 years of Peer Review documents, and the credentialing and privileging files of the three attending general surgeons. The NSO Quarterly Report defines a normal observed to expected (OE) ratio as 1. The 12-month, 30-day, rolling mortality OE ratio for the Medical Center from July 1, 2012 to June 20, 2013 was 1.13, and the OE ratio 90 percent confidence interval for that time period was 0.70 to 1.74.[4] The Medical Center's OE ratio for the 12 months from July 1, 2013 to June 30, 2014, OE ratio was 0.49. The VHA Surgery Program Facility Summary provides a visual and quick reference to concerns identified within the body of the NSO Quarterly Report.

The Handbook outlines the VISN Surgical Work Groups and the Veterans Surgical Quality Improvement Program (VASQIP) Executive Board review of VASQIP outcomes

[4] The confidence level describes the uncertainty associated with a *sampling method.* A 90 percent confidence level means that we would expect 90 percent of the interval estimates to include the population parameter.

for each surgical program. Programs whose outcomes deviate significantly from national averages for mortality or morbidity are further reviewed to determine corrective interventions. VISN or NSO interventions are dependent upon the degree or persistence of quality concerns at a VHA facility and are based on levels of concern. Levels of concern are defined as follows: no concern; emerging concern: a single quarter (3-month period) of mortality outlier status (defined as a statistically significantly high VASQIP mortality OE ratio for all operations); confirmed: one rolling 12-month period of mortality outlier status; ongoing concern: three consecutive quarters of rolling 12-month mortality outlier status; critical concern: six consecutive quarters of rolling 12-month mortality outlier status. The Medical Center's concern scores on both Quality and Safety were zero, meaning that the NSO had no concerns.

In addition to interviewing the surgical staff, VA reviewed surgical documentation of resident supervision. According to VHA Handbook 1400.1, *Resident Supervision*, facilities providing graduate medical education must have a defined process for supervision of those being trained. As defined in this Handbook, the Medical Center staff monitors whether attendings are meeting the supervisory requirements by conducting retrospective reviews of medical records. Per local policy, the quality management staff must conduct chart reviews on at least a quarterly basis for all clinical areas where residents are involved in patient care. The Medical Center's Quality Manager reviews at least 10 surgery records each month. A Resident Supervision Monitoring form is completed for each chart reviewed, and the data are aggregated and presented to the Medical Center Director through the Clinical Executive Board. The reviewer gathers the following information from the EHR.

- Attending's name recorded.
- Documentation of resident supervision in progress note by attending or attending's name in the resident's progress note.
- Inpatient met by attending within 24 hours of admission. Independent progress note or addendum (with findings and concurrence with the resident's initial diagnosis and treatment plan, as well as any modifications or additions) documented no later than the day after admission.
- The attending ensures that discharge or transfer is appropriate. At a minimum, evidence of this will be documented by attending's countersignature of the discharge summary or clinic discharge note.
- Outpatients, seen by, or discussed with, the staff practitioner at time of initial visit. This is documented by the attending, or the resident's note, and includes the name of the staff practitioner and the nature of the discussion.
- Returning outpatients seen by, or discussed with, attending as necessary to ensure treatment is effective and appropriate. This is documented in a note by the attending or the resident's note.
- Attendings are responsible for the supervision of trainees involved in consultation services. The attending will document the consultative supervision in a progress note or by concurrence with the trainee's consultation note.

- For elective or scheduled procedures, the staff practitioner will evaluate the patient and write a preprocedural note describing the findings, diagnosis, plan for treatment, and/or choice of specific procedure to be performed.
- For nonroutine, nonbedside, diagnostic or therapeutic procedures (e.g., endoscopy, cardiac catheterization, etc.), the supervising practitioner was physically present in the procedural area.
- In emergency situations, any resident will be permitted to do everything possible to save the life of a patient or to save a patient from serious harm. The attending must be contacted and appraised of the situation as soon as possible. The resident must document the discussion in the patient's record.

VA reviewed the results from the surgical service at the Medical Center from FY 2011 to 2014:

FY 2011 - 1st quarter: 100 percent (29/29) met requirements.
FY 2012 - 4th quarter: 100 percent (23/23) met requirements.
FY 2013 - 1st quarter: 94 percent (16/17) met requirements. On 10/20/12, 1 surgical medical record did not have an attending note or signature.
FY 2013 – 2nd quarter: 94 percent (16/17) met requirements. On 1/7/13 1 surgical medical record did not have an attending note or signature.
FY 2013 – 3rd quarter: 80 percent (12/15) met requirements on Documentation of resident supervision in progress note by attending or attending's name in the resident's progress note. On 5/8, 5/30 and 5/31/13, 3 surgical medical records did not have an attending note or signature.
FY 2013 – 4th quarter: 100 percent (15/15) met requirements.
FY 2014 – 1st quarter: 80 percent (12/15) met requirements. 1 Surgical Service attending did not have a note or sign or countersign resident notes on 10/29/13, 11/6/13, and 12/19-12/24/13.

VA also reviewed the Office of Academic Affiliations' Annual Reports on Resident Training Programs (AARTP) for the Medical Center for 2012, 2013, and 2014. Results of these reports showed an 100 percent compliance with supervising practitioner note by the end of the calendar day after admission, and 100 percent compliance with surgical attending pre-op note or addendum to resident's pre-op note within 31 days prior to OR procedure.

We reviewed the EHRs of the specific cases the whistleblower described in the OSC letter, to review the degree of involvement by the attending or resident based on documentation in the attending's or resident's progress notes. In all cases, the EHR reflected attending supervision in the operating room for critical portions of the operation.

The whistleblower, during his interview, alleged that OR nurses falsified documentation of resident supervision on the surgical logs in the VistA Surgical Package. VHA's Resident Supervision policy requires documentation of the level of staff involvement in

the computerized surgical log (a part of the VistA Surgical Package) or similar automated system using the following scale:

- **Level A**: Attending Doing the Operation: The staff practitioner performs the case, but may be assisted by a resident.
- **Level B**: Attending in OR, Scrubbed: The supervising practitioner is physically present in the operative or procedural room and directly involved in the procedure. The resident performs major portions of the procedure.
- **Level C**: Attending in OR, Not Scrubbed: The supervising practitioner is physically present in the operative or procedural room. The supervising practitioner observes and provides direction. The resident performs the procedure.
- **Level D**: Attending in OR Suite, Immediately Available: The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.
- **Level E**: Emergency Care: Immediate care is necessary to preserve life or prevent serious impairment. The supervising practitioner has been contacted.
- **Level F**: Non-OR Procedure: Routine bedside and clinic procedure done in the OR. The supervising practitioner is identified.

Although this policy does not define who is responsible for documenting the level of staff involvement, it is the practice of the OR circulating nurse to enter information into the VistA Surgical Package after the surgery is completed. The OR Nurse Manager said that he had not established a policy or SOP that provided guidance on how the documentation is to be done, and that newly assigned nurses learn the process from experienced nurses who have worked in the OR for a long time. All four OR nurses, including the OR Nurse Manager, were very clear on documenting whether an attending was present in the OR, but gave variable responses on selecting between Level A or B, as they were not always sure whether the attending was performing the surgery or assisting the resident with the surgery.

With regard to Room 2, as noted above, nursing staff always confirms the supervising attending prior to the start of the procedure. VA did not find evidence that the nurses falsified the documentation of attending presence in the OR. No physician interviewed was aware of a way to influence this documentation or familiar with how to document attending surgeon participation in VistA, but they all knew that the nurses documented their presence in the OR in some fashion.

The American Board of Surgery's (ABS) training requirements for General Surgery Certification related to graduated responsibility are noted below.

- To be eligible for ABS certification in general surgery, the following must be completed:

Program and Time Requirements

- A minimum of 5 years of graduated residency education satisfactorily completed in a general surgery program accredited by the ACGME or Royal College of Physicians and Surgeons of Canada.
- At least 54 months of clinical surgical experience with increasing levels of responsibility over the 5 years, with no fewer than 42 months devoted to the content areas of general surgery.

Specific Requirements Chief Resident Year

- Acting in the capacity of chief resident in general surgery for a 12-month period, with the majority of the 12 months served in the final year. The term "chief resident" indicates that a resident has assumed ultimate clinical responsibility for patient care under the supervision of the teaching staff and is the most senior resident involved with the direct care of the patient.
- All rotations at the PGY-4 and -5 levels should involve substantive major operative experience and independent decision making.

Operative Experience

- A minimum of 750 operative procedures in 5 years as operating surgeon, including at least 150 in the chief resident year. Applicants may count up to 50 cases as teaching assistant (a senior or chief resident functions as the primary instructor of a junior resident for a particular procedure; an attending surgeon is still responsible for conduct of the procedure) toward the 750 total; however, these cases may not count toward the 150 chief year cases.

Case Minimums

- The ABS and RRC-Surgery have approved the following minimum case requirements:
    - 25 TA Cases: Residents will be required to have participated as teaching assistant in a minimum of 25 cases by the completion of residency. This is effective with applicants completing residency in the 2014–2015 academic year.
    - 250 Cases by PGY-2: Residents will be required to have performed 250 operations by the conclusion of the PGY-2 year. These can include cases performed as surgeon or first assistant, endoscopies, or operative exposures (e-codes*). Of the 250, 200 must be either in the defined categories, endoscopies or e-codes.

VA reviewed VistA records, resident supervision audits, and other documentation in the EHR. VA could find no evidence of a resident in any level of training, even PGY-5, operating unsupervised on major cases.

The NSO Quarterly Report includes the Medical Center's Resident Supervision General Surgery Surgical Case Counts, from July 1, 2013 through June 30, 2014. The number of cases and level of attending involvement were:

Level A	Level B	Level C	Level D	Level E	Level F	Total
195	762	230	52	0	0	1034

These data, which include Room 2 (the minor procedure room), reveal that only 5 percent of all operations are performed with an attending available in the OR suite, but not in the room. No cases were performed without an attending immediately available. Facilities with a clinic OR do not report clinic minor surgery procedures into VASQIP; therefore, these facilities would have a lower rate of reported cases performed by residents only.

1b. Dr. (b) (6) Chief of Surgery, restricted the whistleblower's scope of resident involvement in the operating room and informed the whistleblower that he could not make any distinction on the competency of resident physicians and that he must allow all residents to practice and perform surgery, including complex surgical procedures on patients regardless of their ability.

As the General Surgery Residency Associate Program Director at the Medical Center, Dr. (b) (6) had the responsibility to ensure residents are educated appropriately. Part of that responsibility includes counseling junior attendings about their educational role. The whistleblower provided a copy of a memorandum dated January 8, 2013, in which Dr. (b) (6) encouraged him to (b) (6)
(b) (6)

The residents had presented Dr. (b) (6) with (b) (6)
(b) (6) (especially senior residents) to perform surgery in a manner consistent with the graduated levels of responsibility and independence expected in a residency training program. The majority of the residents interviewed confirmed that these concerns were raised with Dr. (b) (6)
(b) (6), Program Director of the Phoenix Integrated Surgery Residency. The whistleblower's viewpoint was that the (b) (6)
(b) (6) Dr. (b) (6) discussed these issues with the Program Director, and they decided that the (b) (6)
teaching program. This is the context in which Dr. (b) (6) reports sending an email to the whistleblower. Dr. (b) (6) stated that resident physicians had reported to him that the
(b) (6)
(b) (6) Because of this, Dr. (b) (6) said he suggested (b) (6)
(b) (6)

(b) (6) stated that he did not inform the whistleblower that he could not make any distinction on the competency of residents or that he should allow residents to perform surgery regardless of their ability, and the team did not find evidence to confirm this

allegation in the email messages. He did report that he discussed surgical graduated levels of responsibility with the whistleblower.

All other attendings reported that overall the residents in general surgery had very good technical skills and they felt very comfortable teaching them surgical techniques. As noted above, general surgery training involves graduated levels of responsibility and participation. By the time a resident is in PGY-5, there is a teaching assistant requirement (as noted above in the American Board of Surgery training requirements), that they will be able to supervise other residents performing surgery. The General Surgery Program Director stated that he had "been involved in surgery resident and fellow education since 1988 and these are the best group of residents I've had the honor of training. Their commitment to their patients and in particular to Veterans is second to none."

VA reviewed the operative log summaries for all residents graduating from the program in 2012, 2013, and 2014, as reported to the ACGME. The chart includes the national average and the program average for major cases performed (total major), the total number of cases performed by chief surgical residents (total surgeon chief), the total number of cases performed by junior surgical residents (total surgeon junior), and the total number of cases performed as a teaching assistant (total teaching assistant).

Defined Category Cases	2011-2012 National Average	2011-2012 Program Average	2012-2013 National Average	2012-2013 Program Average	2013-2014 National Average	2013-2014 Program Average
Total Major	1000.9	1208.3	1000.4	1167.3	1010.6	1238.2
Total Surgeon Chief	243.9	199.2	237.8	224.5	240.5	234.2
Total Surgeon Junior	736.3	993.0	139.1	929.2	741.7	974.5
Total Teaching Assistant	31.9	18.0	32.5	13.7	33.3	35.4

Surgical residents were especially well prepared in laparoscopic techniques: compared to the national average, all were above 87 percent in number of cases performed and the majority were above 98 percent. The program's number of basic laparoscopic cases is twice that of the national average, and the residents' experience in complex laparoscopic cases also exceeds the national average.

The affiliated Banner Good Samaritan Hospital has the only Fundamentals of Laparoscopic Surgery (FLS) skills laboratory and testing station in Arizona, which reflects the program's commitment to FLS training. Surgery residents from the other

four general surgery programs in the state receive their FLS testing through the Banner Good Samaritan program.

For the last 5 years, all surgical residents completing their training at the Medical Center passed their written boards (the American Board of Surgery Qualifying Exam) on their first attempt, and over 87 percent passed the more difficult orals on their first try. These first-time pass rates for program graduates on written and oral boards are among the highest in the country for programs of this size.

Conclusions for Allegation # 1

- VA **did not substantiate** that residents performed surgeries without supervision, resulting in serious patient complications and outcomes.

- Resident supervision was evaluated using a number of parameters, and VA **did not substantiate** that residents performed major surgery in the Medical Center's ORs without supervision.

- VA did find that minor surgical procedures were sometimes performed by residents without the supervising attending in the room, as is appropriate with graduated levels of responsibility.

- There are no quality or safety issues identified in the NSO Quarterly Reports for the Medical Center from 3rd quarter FY 2013 to 3rd quarter FY 2014. The Medical Center was functioning at an acceptable level when compared with other VA medical centers of similar complexity and size.

- VA **did not substantiate** that records were falsified with regard to attending surgeon presence in the OR.

- VA did find that the OR nurses did not have a consistent way of documenting the attending and resident's level of participation in surgery.

- VA **did not substantiate** that surgical residents may have performed 30 to 40 percent of minor surgeries and 5 percent of major surgeries with no attending surgeon present, in violation of agency policies.

- VA found a minor problem with surgical attending notes and co-signatures, which were identified and addressed by the Medical Center.

- VA **substantiated** that Dr. (b) (6) in his role as Associate Program Director, had appropriately suggested to the whistleblower to (b) (6) to support the training requirements of graduated levels of responsibility.

Recommendations to the Medical Center:

1. Develop an SOP for nursing documentation of attending and resident participation in the OR in the VistA Surgical Package, including the attendings' presence in the OR (as is currently being done), with specific attention to reporting accurately the attendings' and residents' role in the operation (operating versus assisting).

2. Until minor cases are moved to the new clinic procedure room, appropriately classify the procedures done in Room 2 as clinic procedures done in the OR.

3. Continue to conduct Resident Supervision Audits and document corrective actions as needed.

4. Educate all surgical attending staff on the role of graduated levels of responsibility in surgical education, and continue to monitor for appropriate participation.

Allegation # 2

Supervising physicians performed and directed advanced laparoscopic surgical procedures which they were not qualified or trained to conduct or supervise, resulting in serious complications.

2a. He personally observed supervising physicians performing minimally invasive laparoscopic surgeries for which they were not certified or qualified in violation of VA credentialing and privileging policies, and that during the course of these surgeries, attending physicians allowed unqualified residents to conduct the majority of the surgery, beyond their designated levels of responsibility.

Findings

General surgeons perform operations utilizing both open and laparoscopic techniques. General surgeons began using laparoscopic techniques in 1989; those trained before 1989, took courses, and participated in monitoring programs to gain privileges to perform surgery utilizing a laparoscopic technique. At the Medical Center, general surgeons commonly perform procedures utilizing a laparoscopic approach. The Core Physicians' Web site includes as common general surgery procedures: laparoscopic cholecystectomy, laparoscopic colon resection, laparoscopic Nissan fundoplication, and laparoscopic ventral hernia repair. General surgeons are not required to complete an additional fellowship to perform common laparoscopic procedures, but rather they are required to demonstrate competency.

Review of the credentialing and privileging files of the three attending physicians that VA interviewed identified that they all had been granted privileges to perform surgical procedures. VA did note that the Medical Center's list of general surgery privileges is organized in broad categories by organ system, and does not identify specific surgical procedures or techniques (open versus laparoscopic). VA provided the Chief of Staff an

example of a more detailed list of privileges for general surgeons. All attending surgeons reported that the residents in the general surgery training program had a lot of operative experience and were technically skilled.

2b. During surgical morbidity and mortality conferences held in (b) (6) and (b) (6) 2013, Dr. (b) (6) presented two cases where patients suffered surgical incision wound site ruptures, known a "wound dehiscence," due to surgery performed by residents who were unqualified to perform the surgeries and who were not well supervised during the operations.

Findings

Although the whistleblower was unable to provide the names of these Veterans, VA reviewed notes from the M&M conference, one at which the operating surgeon presents his or her complication and other surgeons critically review the indications for surgery, the surgical technique, causes of the complication, in light of a review of the published literature. These notes identified two cases of dehiscence in this time frame. The abdomen is usually closed in two layers; one layer is the fascia and the other is the skin. The fascial layer is the critical layer as the fascia protects and encloses the intraabdominal contents. A dehiscence occurs when the fascia separates, providing an opening through which intraabdominal contents can protrude. Both of these cases were performed by a PGY-5 resident with a supervising "attending present for all of the critical portions of the procedures." VA could find no evidence that these cases were performed by unsupervised residents. Specifically, all residents report that the attending stays in the room until the fascia is closed. Postoperatively, the Veterans developed a dehiscence that providers identified and repaired in the OR. In both cases, the closure suture was intact, but had torn through the patient's tissue. This is a known risk factor for dehiscence. The M&M reviewers concluded the cases were handled appropriately.

2c. In (b) (6) 2013, the whistleblower observed Dr. (b) (6), a VA physician performing a hand-assisted laparoscopic right hemicolectomy, with the assistance of Dr. (b) (6), a second year resident, that Dr. (b) (6) (although a board certified general surgeon) was not properly credentialed or privileged to perform this procedure, and that the surgeon then allowed Dr. (b) (6), who had not previously observed this type of surgery, to perform the majority of the procedure. The patient suffered post-operative peritonitis requiring readmission to the hospital.

Findings

VA reviewed Dr. (b) (6) credentialing and privileging file and determined that he had been granted the same privileges as the whistleblower to perform colectomies. As noted above, the General Surgery privileging forms do not distinguish between open and laparoscopic colectomy. When questioned about this, everyone said that all of the

general surgeons perform both open and laparoscopic procedures and they are part of the general surgery core privileges.

VA reviewed the (b) (6) and (b) (6) 2013 OR schedules in an effort to identify cases in which both Dr. (b) (6) and Dr. (b) (6) were involved. One case performed on (b) (6) 2013, most closely matched the description above.

- On (b) (6) 2013, Dr. (b) (6) performed a hand-assisted laparoscopic recto-sigmoid colon resection with a PGY-5 resident. Hand-assisted laparoscopic surgery colon resection utilizes a special device to allow a hand to be inserted into the abdomen while maintaining insufflation; this may lessen the need for conversion, shorten operative time, and decrease disposable costs while maintaining the benefits of minimally-invasive surgery. Dr. (b) (6) was present for all of the critical portions of the procedure. The resident dictated the operative report, which is usually done when the resident is the principal surgeon. The Veteran was discharged on postoperative day 6, without complications.

- On (b) (6) 2013, Dr. (b) (6) performed a hand-assisted right hemi-colectomy with a PGY-5 resident. Dr. (b) (6) was present for all of the critical portions of the procedure. The resident also dictated this operative report. This Veteran's postoperative course was complicated by bleeding that required a transfusion, but no return to the OR nor readmission to the hospital. He was discharged on postoperative day 8.

- On (b) (6) 2013, the whistleblower and Dr. (b) (6) performed a laparoscopic lysis of adhesions, and a side-to-side ileocolic anastomosis. The whistleblower was present for the entire case. This case was dictated by the resident. The patient was discharged on postoperative day 2.

- On (b) (6) 2013, Dr. (b) (6) and Dr. (b) (6) performed a hand-assisted laparoscopic right hemicolectomy together. The attending was present for the entire case, which was dictated by the resident. This patient did well and was discharged on postoperative day 5. She was readmitted on postoperative day 21, and found to have an intraabdominal abscess. The abscess was drained percutaneously, and she was discharged the next day.

This review highlights that the Medical Center had properly granted Dr. (b) (6) clinical privileges to perform laparoscopic colon surgery.

2d. On (b) (6) 2013, during surgery to remove a necrotic gallbladder remnant and stones, Dr (b) (6) instructed (b) (6) to convert from a laparoscopic to an open procedure, when there was not medical indication or need. Dr. (b) (6) is not privileged or credentialed to perform this type of advanced laparoscopic procedure. In addition, the OSC allegation states the patient's informed consent was for the laparoscopic procedure, not open, and

therefore the patient did not provided informed consent for this type of procedure. And Dr.(b) (6) orders directly contravened the patient's wishes with regard to the type of surgery and constituted a violation of VA policy.

Findings

VA interviewed all three attending surgeons (including the whistleblower) involved in this case and reviewed pertinent documents, including their credentialing and privileging files, the informed consent form, the anesthesia record, and the operative report.

All three attending surgeons have been granted privileges to perform gallbladder surgery. Cholecystectomy is a basic laparoscopic procedure and is usually the first laparoscopic procedure learned in a general surgery residency. During his interview, the whistleblower acknowledged that a cholecystectomy is a basic laparoscopic procedure.

In(b) (6) 2013, the Veteran presented with an exacerbation of chronic abdominal pain. His past medical history is significant for a removal of an infected gallbladder 20 years previously, at which time the surgeon had attempted to remove it laparoscopically but had converted to an open procedure. Prior surgery, especially associated with an infection, causes scarring and adhesions that can make reoperation more difficult.

Imaging studies in(b) (6) 2013, revealed inflammation of either a remnant of the gallbladder or a cystic duct stump with gallstones. Nonoperative management was attempted at first, but the Veteran continued to experience symptoms. He then received preoperative counseling and signed an informed consent document for "Gallbladder-Cholecystectomy (laparoscopic), Cholecystectomy (open), Cholecystectomy (open) with common bile duct exploration."

On(b) (6) 2013,(b) (6) noted in the EHR that he had counseled the Veteran about the risks of surgery and "discussed....laparoscopic and open." When asked about the allegation that the Veteran had not been counseled for an open procedure or discussed the informed consent document the Veteran had signed, the whistleblower recanted the allegation and acknowledged that the patient had been counseled about the possibility of conversion to an open procedure.

The operative report, dictated by(b) (6) notes that "during the procedure, I have requested for a second opinion to look at the CT scan with(b) (6) ...we concluded that we are on the right track except that is a little bit difficult because of the excessive adhesions."(b) (6) reported to VA investigators that he had recommended to(b) (6) to convert the operation to an open procedure; however,(b) (6) continued to attempt to complete the surgery laparoscopically. Due to his concern for the Veteran, secondary to lack of progress of the operation, the amount of adhesions and scarring, and prolonged anesthesia time,(b) (6) spoke with(b) (6) the Chief of Surgery.(b) (6) reports that he went to the OR and assessed the situation. The Veteran had been on the table for almost 4

hours and the gallbladder was still not exposed for resection. (b) (6) recommended conversion to an open procedure and volunteered to assist. The anesthesia record notes that the surgery started at 8:00 a.m., the procedure was converted to open 228 minutes later at 11:48 a.m., and completed at 2:10 p.m., after more than 6 hours on the OR table.[5] (b) (6) completed the open procedure uneventfully with (b) (6) assistance. The patient did well postoperatively and was discharged on postoperative day 3.

Conclusions for Allegations # 2

- VA **did not substantiate** that attending surgeons were performing procedures that they were not privileged to perform.

- Dr. (b) (6) and Dr. (b) (6) did perform a hand-assisted laparoscopic colon resection which developed a postoperative leak, which was identified and managed appropriately.

- The Medical Center's General Surgery privileging categories were based on organ systems and not on the technique used (open versus laparoscopic).

- VA **did not substantiate** that residents were allowed to perform surgery with inadequate supervision.

- Both the Chief of Surgery's and the other attending's recommendation to convert the (b) (6), 2013, Veteran's gallbladder surgery to an open procedure was appropriate in view of the technical difficulty of the case, the extended duration of the operation, and the risks associated with prolonged anesthesia.

- VA **did not substantiate** that the Veteran had not granted informed consent for conversion to an open procedure.

- VA **did not substantiate** that Dr. (b) (6) orders directly contravened the patient's wishes with regard to the type of surgery and constituted a violation of VA policy.

Recommendations to the Medical Center:

5. Revise the current list of clinical privileges in general surgery to include technique (i.e., open and/or laparoscopic).

6. Review Dr. (b) (6) colon leak rates against national standards.

Recommendation to VHA:

[5] An article in the *Journal of the Society of Laparoendoscopic Surgeons*, 2002, Apr-Jun: 6(2): 149-154, reports the mean time for an acute (inflamed) cholecystectomy was 94 minutes (with a range of 55-154 minutes.

7. Develop a standardized template that facilities could utilize for its general surgery privileging forms, to ensure inclusion of technique (i.e., open and/or laparoscopic).

Allegation # 3

Beginning in March 2012, employees repeatedly accessed Dr. (b) (6) medical records for unknown reasons and without cause constituting both an impermissible intrusion into his privacy and a violation of law and agency policy.

Findings

VHA Handbook 1605.02, *Minimum Necessary Standard for Protected Health Information*, provides guidance on the procedures for determining the minimum necessary amount of Protected Health Information (PHI) that members of the VHA workforce may access, use, disclose, or request and defines the assignment of Functional Categories (Appendix B) to VHA employees. These functional categories obligate employees to access the minimum data necessary to perform their official job duties. In addition, the procedures in this handbook comply with the minimum necessary requirements in the Standards for Privacy of Individually-Identifiable Health Information, title 45 Code of Federal Regulations, Parts 160 and 164 (Privacy Rule) promulgated by the Department of Health and Human Services under the Health Insurance Portability and Accountability Act.

At the time VA police officers accessed the whistleblower's VistA record, VA Handbook 1605.02, Appendix A, provided the following access:

Functional Categories (Class of Persons): Security;
Type of Protected Health Information Accessible: Entire Medical Record including research records.
Conditions for Access to Information: Monitoring and tracking of security issues.
On January 23, 2013, VA modified VA Handbook 1605.02 and nationwide police officers no longer have access to patient records. Only the Chief of Police at the facilities has limited access to the health record necessary to complete a task, (i.e. identifying disruptive patients that require police escort while at the facility).

Employee unauthorized access to coworker and Veteran's EHR is a high priority for VHA. On June 20, 2014, Health Information Governance (HIG), under the Office of Informatics and Analytics, proposed to Clinical Operations (10N) four actions to address the issue. They added a fifth action as a result of OSC's requests for investigations of unauthorized access.

1. VA developed a message for all VHA employees to remind them of their responsibilities to have a legitimate need for information prior to access. The message was sent to the VISN Directors for distribution to all staff on September 17, 2014.

"Employees
Subject: Appropriate Access to PII/PHI

VHA employees must comply with all Federal laws and regulations, VA regulations and policies, and VHA policies regarding the confidentiality and privacy of Veteran and employee records. In addition, all VHA employees must conduct themselves in accordance with the rules of ethical conduct. Personally Identifiable Information (PII) and PHI on Veterans and employees should only be collected, accessed, or viewed by VHA employees with a need for that information in the performance of their official VA duties. VHA employees should not access or view the PII/PHI of their coworkers or Veterans out of curiosity or for any purpose that is not related to official VA duties. Also, Supervisors may not view the medical records of their employees who are Veterans to look at their clinic appointments or other medical information for employment-related purposes.

VHA employees who collect, access, or view PII/PHI on Veterans or employees for purposes other than those for official VA duties, including curiosity, are subject to disciplinary action. Even if the VHA employee had good intentions in accessing or viewing the Veteran or employee information, such as to look up a home address to send a sympathy card, it is a privacy breach and disciplinary action may result.

If you have questions regarding the appropriate access to PII/PHI, please contact the facility Privacy Officer at (appropriate telephone number) or via email at (appropriate email address).

(appropriate NAME)
Medical Center Director"

2. The Privacy Office developed information posters, sent on February 14, 2014, to VA Medical Centers and CBOCs to be printed and displayed throughout the facilities.
3. HIG [Health Information Governance] revised the language for the Sensitive Record Warning in VistA. It submitted a new service request (NSR) with the revised language along with other suggestions to modify the Sensitive Record Warning and Office of Information and Technology is processing the request.
4. HIG evaluated updating the Table of Adverse Penalties to more accurately address unauthorized access. It spoke to various other entities, including Department of Defense, Indian Health Service, Centers for Disease Control, National Institutes for Health and Kaiser Permanente, regarding their disciplinary action policies around employee unauthorized access. On December 2, 2014, HIG met with (b) (6) VA's Director of Employee Relations, to discuss these penalties. The final determination was that the Table of Adverse Penalties did not need to be revised, and a VA/VHA HR workgroup is developing joint guidelines and training to be evaluated by VHA supervisors and HR staff. Results will be briefed to the USH, on January 9, 2015.

5. Privacy Compliance Assurance (PCA) has created unauthorized access questions for use during on-site privacy and records management assessments for FY 2015. PCA developed these questions to address a recommendation from VA's reports to the OSC on Northport (DI-14-0838/DI-14-1959).

The whistleblower indicated that he filed a request for his Sensitive Patient Access Report (SPAR) in response to [redacted] The report showed that his EHR had been accessed four times by three different individuals, as follows: "[redacted], VA Police Officer, [redacted], 2012 2:13 p.m., [redacted], 2012 2:13 p.m.; [redacted] VA Police Officer, [redacted], 2012, 11:13 a.m.; [redacted], Administrative Assistant, [redacted], 2013, 8:05 a.m."

On November 4, 2014, VA requested that the Information Security Officer print a SPAR on the whistleblower. The report revealed a total of 12 Medical Center employees who had accessed the whistleblower's EHR from [redacted] 2012, through [redacted] 2014. VA investigated each entry named on the SPAR, and asked the VA Central Program Office Privacy Officer to determine whether there had been privacy violations with these following accesses:

- [redacted], Medical Support Assistant, created the whistleblower's original EHR on [redacted], 2012, for the purpose of setting up an employee physical in anticipation of the whistleblower's entrance on duty. A member of the investigative team verified with the Medical Center's ISO that Mr. [redacted] performed duties as a relief Employee Health Clerk.
- [redacted], Police Officer, accessed the whistleblower's EHR on [redacted], 2012. This officer filed a police report concerning an incident in which the whistleblower had requested assistance from the police for a patient who had become agitated. The police officer accessed the record to obtain the whistleblower's work address and phone number.
- [redacted], Administrative Assistant to the Chief of Staff, accessed the whistleblower's VistA record on [redacted], 2013. In Ms. [redacted] role as Secretary to the Chief of Staff, she has access to patient records for purposes of drafting replies or directing incoming correspondence, including patient complaints, to the appropriate patient care area, and to obtain information to execute the official duties of the Chief of Staff's office. Ms. [redacted] explained in interview that she used VistA to obtain the whistleblower's home address for purposes of sending correspondence. VA found that the whistleblower was [redacted] from the Medical Center after his [redacted], and that Ms. [redacted] sent a letter to the whistleblower on [redacted], 2013, the same date the whistleblower's record was accessed.

The other nine employees who accessed the whistleblower's EHR did so for the purpose of health care operations or to obtain demographic information:

- (b) (6), Assistant Chief, Health Information Management Section, (Medical Records Administrator), retired the whistleblower's pre-employment EHR on (b) (6), 2012, after completion of the pre-employment physical.
- (b) (6), Medical Support Assistant, (b) (6), accessed the EHR for the whistleblower on (b) (6), 2013.
- (b) (6) File Clerk, Health Information Management, accessed the whistleblower's EHR on (b) (6), 2014.
- (b) (6), Program Analyst, Ambulatory Care Service and former Medical Support Assistant for the (b) (6) Clinic and (b) (6) Services, accessed the EHR for the whistleblower on (b) (6) 2013.
- (b) (6), Licensed Practical Nurse, accessed the whistleblower's EHR on 10 occasions from (b) (6) 2012, through (b) (6), 2014. Ms. (b) (6) worked in the Employee Health Unit during this time, and she made several notes in the whistleblower's record.
- (b) (6), RN, (b) (6) Nursing Services, accessed the whistleblower's EHR on (b) (6), 2013. Ms. (b) (6) made clinical notes in the record regarding the whistleblower's care.
- (b) (6), Pharmacist Clinical Specialist, Pharmacy Service, accessed the whistleblower's EHR on (b) (6), 2013. Mr. (b) (6) made clinical notes in the record regarding Dr. (b) (6) care.
- (b) (6), Pharmacy Technician, also accessed the whistleblower's EHR on (b) (6), 2013.
- (b) (6), Police Officer, accessed the EHR on (b) (6), 2012. The purpose of this access was to obtain verification of employee status and home address, (b) (6) (b) (6) (b) (6)

In accordance with the Handbook, Appendix B, Functional Categories Identifying Appropriate Levels of Access to Protected Health Information, and the Functional Categories ("Direct or Indirect Care Providers") that the Medical Center assigned to the above employees, VA concludes that each occasion for accessing the whistleblower's EHR was authorized and appropriately conducted in the performance of these employees' official job duties.

Conclusions for Allegation # 3

- VA **did not substantiate** that employees repeatedly accessed the whistleblower's medical records for unknown reasons and without cause constituting both an impermissible intrusion into his privacy and a violation of law and agency policy, because all were authorized accesses in the performance of the employee's official duties.

- Although not a violation of law or policy, VA should consider alternatives for obtaining employee information (i.e., demographic) necessary for health care operations other than through accessing the VistA EHR.

Recommendation to the Medical Center

8. Explore and implement ethically sound practices to better protect employee privacy and engender trust in VA.

Recommendation to VHA

9. The Privacy Office and the National Center for Ethics in Health Care should review its policy related to accessing VistA EHR to obtain employee demographic information.

VI. Summary Statement

VA has developed this report in consultation with other VA and VHA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement, an abuse of authority, or was a risk to public health or safety. In particular, OGC has provided a legal review and OAR has examined the issues from an HR perspective, establishing individual accountability, when appropriate, for improper personnel practices. VA did not find any violations of law, rule or regulation, abuse of authority, or risk to public health and safety.

Attachment A

Documents Reviewed by VA:

- VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012.
- VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.
- VHA Handbook 1605.1, *Privacy and Release of Information*, May 17 2006.
- VHA Handbook 1605.02, *Minimum Necessary Standard for Protected Health Information*, January 23, 2013.
- VHA National Surgery Office, Medical Center VASQIP data, FY2013 (4 reports) and FY 2014 (3 reports).
- Medical Center Memorandum NO. ES-15, Resident Supervision, August 24, 2007.
- Medical Center Policy Memorandum No. 11-25, Credentialing and Privileging, April 1, 2013.
- Medical Center Policy Memorandum PO-05, Sensitive Record Access and Tracking Policy, June 6, 2014.
- Medical Center Policy Memorandum PO-05, Sensitive Patient Access Report (SPAR), Appendix A –SOP, June 6, 2014
- Medical Center Memorandum PO-01, Privacy Policy, September 24, 2013.
- Surgical Service Staff Meeting Minutes, January 2013 – September 2014.
- Physician credentialing and privileging files, including those of three general surgery attending physicians
- Surgical Peer Reviews (January 2013-January 2014)
- Surgical Service M&M Minutes, September 2013 – August 2014.
- Surgical Service Invasive Procedure Minutes, (October 25, 2012, March--November 2013, and February 2014).
- Resident Supervision Audits 4th quarter FY 2012, 1st -4th quarter FY 2013, and 1st quarter 2014.

- Veterans' EHRs
- Whistleblower's SPAR, January 2012 – November 2014
- Medial Center Police Report by (b) (6) Police Officer, November 8, 2012