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The Special Counsel

December 20, 2013

The President
The White House
Washington, D.C. 20500

Re: OSC File No. DI-11-3203

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), enclosed please find agency reports based on disclosures made by a whistleblower at the Department of Veterans Affairs (VA), Central Arkansas Veterans Healthcare System, John L. McClellan Memorial Veterans Hospital (Medical Center), Little Rock, Arkansas. The whistleblower, Cindra Flowers, who consented to the release of her name, was employed as a Radiologic Technologist (RT) at the Medical Center. She alleged a number of serious health, safety, and management breaches, including poor inventory management in the Imaging Service Department, inadequate cleaning and infection control practices, failure to reconcile medications when administering contrast agent to patients, and violations of patients' privacy rights.

The agency investigation substantiated most of Ms. Flowers's allegations and agreed that these were significant issues that must be corrected. The report confirmed that expired supplies were present in the computed tomography (CT) and interventional radiology (IR) rooms; cleaning and infection control was inadequate in the CT and IR rooms; and information disclosures in the Imaging Service Department violated the Privacy Act of 1974, 5 U.S.C. § 552a (the Privacy Act), and the Health Insurance Portability and Accountability Act (HIPAA).

The investigation also substantiated that on one occasion, suction equipment was unavailable when it was needed to treat a patient who later died. The report found that there was not enough evidence to sustain or refute the whistleblower's allegation that the lack of available equipment caused the patient's death. Upon review of the actions of the medical staff prior to the incident, the agency concluded that the medical care provided to the patient met the standard of care.

The agency reports identified the corrective actions taken at the Medical Center in response to the investigation, including re-training those responsible for restocking supplies. While the agency report contains all the information required by statute and the findings appear reasonable, I note that the VA did not fully respond to the allegations regarding a lack of available suction equipment in the CT room and the death of one patient until eight months after my initial request. Such delays needlessly impede OSC's statutorily mandated public reporting.

Pursuant to 5 U.S.C. § 1213(e)(1), Ms. Flowers provided comments on the Secretary's findings. Although the agency substantiated most of her allegations, Ms. Flowers expressed general dissatisfaction regarding the outcome of the investigation. Specifically, Ms. Flowers expressed disappointment that individuals she believes were responsible for the deficiencies in the provision of care were not held accountable, and she was skeptical that the corrective actions called for in the agency report would occur. Moreover, during the time she was employed at the Medical Center following the agency's report, she continued to observe and document the failure to keep crucial supplies stocked and available in the CT rooms as needed. As required by 5 U.S.C. § 1213(e)(3), I am now transmitting the agency reports and whistleblower comments to you.[1]

I. Poor Inventory Management

Ms. Flowers disclosed that there are local supply cabinets throughout the Imaging Services Department that are maintained solely by the employees who work in that Department. Ms. Flowers explained that the local supply cabinets located in both CT and IR rooms are not adequately stocked and inventory is not rotated effectively. On multiple occasions, from approximately 2009 through 2011, Ms. Flowers discovered and removed from the CT room cabinet a large number of expired supplies, with expiration dates from 2003 to the present. In addition, she observed other RTs disposing trash bags full of expired supplies. According to Ms. Flowers, if the supplies maintained in the CT and IR room cabinets had been rotated effectively, they would have been used before their expiration, and therefore, fewer supplies would have had to have been discarded.

Ms. Flowers added that because the responsible employees fail to verify regularly the inventory in the CT and IR rooms, essential supplies for patient care are out of stock. She disclosed that in 2011, a patient she was treating began to vomit while on the exam table in a CT room. She alleged that the CT room was not properly stocked with suction canisters and tubes, a heart rate monitor, and a blood pressure cuff. Ms. Flowers believed the lack of essential supplies resulted in this patient aspirating[2] on his vomit; he died the following day.

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[1] The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation, gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c).

Upon receipt, the Special Counsel reviews the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). The Special Counsel will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

[2] To aspirate means to inhale into the airways foreign material, such as vomitus.

The OMI substantiated Ms. Flowers's allegation that there were expired supplies in the CT and IR room supply cabinets, by as much as three months. The agency report explains that the Lead RT is responsible for reviewing the expiration dates on all supplies and removing expired supplies at least once per month. In response, the Medical Center conducted training for appropriate personnel, and OMI recommended that the Medical Center better enforce its policies and procedures for discarding expired supplies.

Although the OMI did not substantiate Ms. Flowers' allegation that essential supplies for patient care were out of stock in the CT and IR rooms, it confirmed that at the time of the event described above, the CT room was not stocked with all needed supplies, such as suction equipment. The OMI could not substantiate Ms. Flowers's allegation that the patient aspirated due to the lack of available suction equipment, asserting that the patient's preexisting medical condition was a significant factor in his death. However, the OMI recommended a peer review of the event.

In January 2013, OSC requested supplemental information from the VA to determine whether a peer review had been conducted and, if so, its outcome. After a second OSC request, the VA responded that the facility conducted a peer review, but was prohibited by 38 U.S.C. § 5705, relating to the confidentiality of medical quality assurance records, from disclosing the outcome of the review.[3] Thus, the VA refused to provide OSC with the review itself or even its outcome.

OSC strongly disagreed with the VA's position, but in an attempt to learn basic information, in February 2013, OSC requested the following information: (a) whether the peer review provided additional evidence that would allow the VA to either sustain or refute the whistleblower's allegation that the patient aspirated due to the lack of available suction equipment; (b) a description of the additional evidence and updated findings on this allegation; and (c) following the peer review, what, if any action was taken or recommended. As a compromise, the VA agreed to the re-investigation of the subject of the quality assurance review by the Veterans Health Administration, and to file with OSC a written report of its findings in a manner that did not implicate the disclosure limitations of 38 U.S.C. § 5705. The report, entitled "Unprotected Management Review for the Office of Special Counsel," offered no new information. About the particular matter that was the subject of the peer review, the report stated, "[T]he medical care provided by the clinical team meets the standard of care."

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[3] The VA stated that 38 U.S.C. § 5705(b)(1)(C) allows disclosure of quality assurance documents "to a criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of such agency or instrumentality makes a written request that such record or document be provided for a purpose authorized by law." The VA asserted that its understanding is that when acting under the authority of 5 U.S.C. § 1213, OSC is not a criminal or civil law enforcement governmental agency or instrumentality charged with the protection of public health or safety. In short, the VA maintains that OSC has no enforcement authority, but only the authority to require an agency investigation/report. OSC strongly disagrees. 5 U.S.C. § 1213(a)(1)(B) invokes OSC's authority to receive and act on disclosures by employees involving a "substantial and specific danger to public health or safety."

II. Inadequate Infection Control

Ms. Flowers also disclosed that cleaning and infection control is inadequate in the Imaging Services Department. She explained that invasive procedures are performed on a regular basis in both the CT and IR rooms, and thus that the rooms need to be sterilized before a new patient is brought in. Nevertheless, the Environmental Management Services (EMS) employee assigned to the Imaging Services Department cleans each room in the Department only once daily, and not until after 12:30 p.m. According to Ms. Flowers, because of the infrequent cleaning, there is blood on the floor, and trashcans and laundry bins regularly overflow. She described an event on Sunday, October 16, 2011, in which EMS had not cleaned the CT or IR rooms since the preceding Friday. That Sunday, Ms. Flowers observed a RT moving full trash bags and laundry bags from the IR room into the hallway and cleaning the room herself. In addition, Ms. Flowers disclosed that employees failed to follow the infection control policies established to ensure compliance with Joint Commission[4] standards. For example, she indicated that procedure tables were not cleaned immediately after each sterile procedure and that employees in the room during invasive procedures did not all wear caps and masks.

The OMI substantiated the allegation that cleaning and infection control was inadequate in the CT and IR rooms, that EMS only cleaned each room once daily and not until 12:30 p.m., and that the rooms were not cleaned after each procedure. The OMI also substantiated Ms. Flowers's allegation that EMS failed to provide cleaning services for CT and IR rooms on the weekend of October 14-16, 2011. The OMI did not substantiate the allegation that employees failed to follow infection control policies and observed that Imaging Service Department employees were consistently cleaning tables and equipment exposed to secretions or blood and were wearing gowns, caps, and masks when required.

In response to the inadequate cleaning and infection control by EMS, the Medical Center instituted an on-call system for cleaning issues needing immediate service, with a response time of 15 minutes on weekdays, and 30 minutes on nights and weekends. Additional EMS shifts were also established. EMS and Imaging Services are now required to report the status of cleaning and infection control to leadership on the first Monday of each month.

III. Failure to Properly Reconcile Patient Medications

Ms. Flowers explained that RTs are responsible for screening patients for possible drug interactions and contraindications prior to administering contrast agents for radiologic studies. Patients taking the oral anti-hyperglycemic medication Metformin are supposed to be instructed not to take the medication for 48 hours after receiving iodinated intravenous

[4] The Joint Commission is an independent, not-for-profit organization that accredits and certifies health care organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx

contrast material because of the risk of contrast-induced renal dysfunction. The patients are also to receive this instruction in writing. Ms. Flowers disclosed that her co-workers did not consistently review patients' medical records to determine whether the patients were taking Metformin, and therefore, did not advise patients properly about the risk of contrast-induced renal dysfunction.

The OMI did not substantiate this allegation. The OMI reported that it interviewed the individuals identified by Ms. Flowers as well as others who work in the Imaging Services Department, and reviewed reports of adverse events and a random sample of 10 out of the 87 patients who took Metformin and had a CT scan with injection of iodinated contrast in October and November 2011. The OMI concluded that Medical Center employees provided appropriate guidance to veterans.

IV. Violation of Patients' Privacy Rights

Ms. Flowers alleged that patients waiting to be treated in the CT rooms were lined up on stretchers or in wheelchairs in the hallway and that it was common practice for her co-workers to interview patients and to obtain consent for procedures in this common area when other patients were present. The Veterans Health Administration (VHA) is a covered entity as defined by the HIPAA Privacy Rule. 45 C.F.R. § 160.103. As such, VHA is required to have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information. 45 C.F.R. § 164.530. According to Ms. Flowers, discussions with individuals about their medical history and pending procedures in open areas and in the presence of other patients is not a practice that ensures the reasonable safeguard of that individual's health information, and thus violates the patient's right to privacy under HIPAA.

The OMI substantiated the allegation that staff obtained informed consent from non-ambulatory patients on stretchers or in wheelchairs in an alcove located in the hallway outside the CT and IR procedure rooms, creating an information disclosure issue that possibly violates both the Privacy Act and HIPAA. The agency reports that the Medical Center immediately implemented a *Temporary Patient Privacy Action Plan*, which included using a room adjacent to the CT and IR rooms to obtain informed consent with complete privacy. In addition, a construction contract was awarded on September 29, 2012, and work began in October 2012 to implement the *Long-Term Privacy Action Plan* referenced in the agency report, involving changes to the physical plant. The project was fully operational as of May 2013.

V. Findings

I have reviewed the original disclosure, the agency reports, and Ms. Flowers's comments. Notwithstanding the proposed corrective actions, the agency report fell short of fully responding to allegations of a substantial and specific danger to public health in regard to the lack of available suction equipment in the CT room and the death of one patient. The report *could not substantiate* that the patient aspirated due to the lack of available suction

equipment, but called for a private peer review of the patient's care to further evaluate the incident.[5] Indeed, if the peer review did not consider whether the lack of equipment led to an adverse patient outcome, the report's conclusion that "the medical care provided by the clinical team meets the standard of care" is conclusory and meaningless with regard to the allegation presented. While the agency report contains all the information required by statute and the findings appear reasonable, I note that the VA did not fully respond to the allegations regarding a lack of available suction equipment in the CT room and the death of one patient until eight months after my initial request. Such delays needlessly impede OSC's statutorily mandated public reporting.

As required by 5 U.S.C. § 1213(e)(3), I have sent unredacted copies of the agency reports and the whistleblower's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans Affairs.[6] I have also filed a redacted copy of the reports and the whistleblower's comments in our public file, which is now available online at www.osc.gov. This matter is now closed.

Respectfully,

Carolyn N. Lerner

Enclosures

[5] According to the VA report, the Medical Inspector returns a finding of "***could not substantiate***" allegations when there is "no conclusive evidence to either sustain or refute the allegations."

[6] The VA provided OSC with a report containing employee names (enclosed), and a redacted report in which employees' names were removed. The VA cited Exemption 6 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(6)) as the basis for its redactions to the report produced in response to 5 U.S.C. § 1213, and requested that OSC post the redacted version of the report in our public file. OSC objects to the VA's use of FOIA to remove these names because under FOIA, such withholding of information is discretionary, not mandatory, and therefore does not fit within the exceptions to disclosure under 5 U.S.C. § 1219(b), but has agreed to post the redacted version as an accommodation.