U.S. OFFICE OF SPECIAL COUNSEL
1730 M Street, N.W., Suite 218
Washington, D.C. 20036-4505
202-254-3600

October 20, 2010

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

Re: OSC File No. DI-09-3272

Dear Mr. President:

Pursuant to 5 U.S.C. § 1213(e)(3), the Office of Special Counsel (OSC) is forwarding to you agency reports concerning disclosures from a whistleblower at the Department of Veterans Affairs (VA), G.V. (Sonny) Montgomery Medical Center (Jackson VAMC) in Jackson, Mississippi. The whistleblower, who requested anonymity, alleged that employees at the Jackson VAMC consistently fail to sterilize medical instruments between uses, and that as a result, patients and staff have been exposed to infectious viruses and bacteria on a regular basis for a number of years.

These disclosures were referred to the Honorable Eric K. Shinseki, Secretary of Veterans Affairs, to conduct an investigation pursuant to 5 U.S.C. § 1213(c) and (d). Secretary Shinseki tasked the Veterans Health Administration (VHA) with conducting the investigation. We received a report dated May 5, 2010, and supplemental reports dated June 10, 2010, July 12, 2010, and August 10, 2010. The whistleblower provided comments on the reports to this office pursuant to 5 U.S.C. § 1213(e)(1). As required by law, 5 U.S.C. § 1213(e)(3), we are now transmitting the reports and the whistleblower's comments to you.

The whistleblower explained that stainless steel medical instruments are ordered through the Supply, Processing, and Distribution Section (SPD). Pursuant to VA Office of Occupational Safety and Health (OSH) Standard Operating Procedure (SOP) 3003, after the instruments are used for a medical procedure, they must be cleaned of gross contamination such as tissue or blood clots and placed into a collection container to be picked up by an SPD employee. The whistleblower indicated that such pickups should occur at least once a day. Upon arrival in SPD, the decontamination process begins by rinsing and cleaning the instruments of blood, bone, and other matter. After cleaning, the instruments should be packed individually with a pressure-sensitive sensor and placed into a high-pressure sterilization unit. When properly sterilized, the sensor changes colors, indicating that the instruments are ready to use. The packaged instruments are then stamped with a sterilization expiry date, and placed onto trays to be distributed accordingly to the clinics within the hospital.

The whistleblower alleged that doctors and staff at the Jackson VAMC do not follow OSH SOP 3003 when cleaning used instruments. Instead, instruments within the Jackson VAMC are

used on patients for procedures including minor surgeries and then, instead of being returned to SPD to be properly decontaminated, individually bagged, sterilized, and dated, they are merely wiped with a Sani-Wipe and re-used on the next patient. Doctors and staff regularly exhaust their supplies of clean instruments before they are finished seeing patients, and choose to reuse instruments to see more patients. The whistleblower claimed to have witnessed on a daily basis nurses and doctors carrying trays of unsterilized instruments into examination rooms, using them on patients, and then placing them back into a drawer for reuse. The whistleblower also reported allegedly cleaned instruments that had dried blood on them, were improperly sterilized, or were sterilized but not individually bagged to preserve sterilization. Examples of these instruments include but are not limited to: scalpels, blade handles, tissue and nail nippers, hemostats, and bone cutters.

The whistleblower alleged that management officials were aware of this continuing public health danger but took no action to address the problem. As a result of this lack of oversight, the whistleblower believed that thousands of veterans, many of whom have compromised immune systems, were potentially exposed to a wide variety of infectious viruses and bacteria without their knowledge. These include Human Immunodeficiency Virus, or HIV, Hepatitis, methicillin-resistant Staphylococcus aureus, or MRSA, bacterial-fungal infections, and warts. The whistleblower also claimed that those veterans were not notified of their possible exposure or tested for any infection that may be a result of such exposure.

In its report, the agency substantiated the allegation that dirty and rust-stained instruments are being distributed to clinics and operating rooms at the Jackson VAMC. However, the agency stated that on occasions when dirty instruments were distributed, staff discovered them prior to use and replaced them with clean instruments. The agency explained that the facility is aware that dirty instruments are being distributed, and is employing both the Operating Room and the Reusable Medical Equipment (RME) Oversight Committees to oversee cleaning and sterilization processes within the Jackson VAMC. The agency noted that despite these sterilization problems, the Jackson VAMC does follow OSH SOP 3003. However, the report stated that on August 13, 2009, an improperly prepared tray was delivered to an operating room by a Medical Supply Technician, and that disciplinary action was pending against that employee.

The agency's report also noted that prior to 2006, providers in the podiatry clinic did experience frequent instrument shortages, resulting in the reuse of unsterilized instruments, but that this problem was resolved with the purchase of additional instruments. The agency convened a Pre-Clinical Risk Assessment Board (Pre-CRAAB), to determine whether the possible exposure to veterans prior to 2006 required that notice be given regarding possible infection. The Pre-CRAAB determined that the risk to patients was negligible and that notice was not required.

In response to these allegations, the agency stated that it would follow up with the Jackson VAMC to ensure full compliance with proper cleaning and sterilization processes. The Jackson VAMC also committed to paying close attention to equipment issues within the podiatry clinic, and to purchasing a new type of instrument and evaluating the chemicals in the instrument washer to ensure cleanliness. A podiatrist was added to both leadership rounds and the RME

Oversight Committee and a quality manager was hired for RME. In addition, the Jackson VAMC began the hiring process to fill the positions of Chief and Assistant Chief of SPD, as well as six Full-Time Equivalent support positions. The hospital also pledged to assess the learning needs of current SPD staff and to provide them with training and assistance in achieving certification.

In its first supplemental report, dated June 10, 2010, the agency clarified that the Medical Supply Technician who prepared the unsatisfactory operating room tray received a proposed 14-day suspension, which was ultimately reduced to 7 days. In its second and third supplemental reports, dated July 12, 2010, and August 10, 2010, the agency responded to OSC's inquiries regarding how the Pre-CRAAB was conducted, who was involved, and how it determined that affected veterans did not require notice of possible exposure. The agency explained that the Pre-CRAAB was comprised of VA staff from headquarters in Washington, D.C. and local staff from the Jackson VAMC. The agency stated that it used VHA Directive 2008-02, Disclosure of Adverse Events to Patients (January 18, 2008) as the basis for conducting the Pre-CRAAB and for its conclusion that notice to veterans was not necessary. In its third supplemental report, the agency noted that VHA does not have formal Standard Operating Procedures for how to conduct a Pre-CRAAB assessment, but rather provides informal written guidance, which was forwarded to participants in this instance. The agency clarified that the Pre-CRAAB involved discussion between local and national staff and an information presentation by the Director of the Jackson VAMC.

The whistleblower submitted comments in response to the agency's report and supplemental reports. In those comments, the whistleblower stated that although the agency has continuously attempted to address the problem of contaminated instruments for over a decade, the problem still exists at the Jackson VAMC. The whistleblower expressed the belief that this is due to a lack of accountability on the part of management. Specifically, the whistleblower noted that many of those who participated in the Pre-CRAAB assessment are directly responsible for allowing the problem of contaminated instruments to continue, creating a conflict of interest in the process of concluding that notice to veterans is not necessary in this case.

OSC has reviewed the original disclosures, the agency's report, supplemental reports, and the whistleblower's comments. Based on that review, we have determined that the reports contain all of the information required by statute and that the agency's findings appear to be reasonable. Notwithstanding this finding, we note with concern the whistleblower's comments that the Jackson VAMC continues to distribute instruments which have not been properly cleaned and sterilized. Furthermore, we believe that the Pre-CRAAB process, as described by the agency, could be compromised by the involvement of management officials who are potentially directly responsible for allowing the underlying conduct to continue. While we trust that no undue influence was present in the decision-making process related to these specific allegations, we note that an emphasis on integrity throughout the Pre-CRAAB process is critical to the quality of care that veterans receive.

As required by law, 5 U.S.C. § 1213(e)(3), we have forwarded copies of the agency's report, supplemental reports, and the whistleblower's comments to the Chairmen and Ranking

Members of the Senate Committee on Veterans' Affairs and the House Committee on Veterans' Affairs. We have also filed copies of the report revised by the VA[1], the agency's supplemental reports, and the whistleblower's comments in our public file, which is available online at www.osc.gov, and closed this matter.

Respectfully,

William E. Reukauf
Associate Special Counsel

Enclosures

[1] The VA provided OSC with a revised report, which substituted the name of the employee involved in assembling an improper instrument tray for the employee's title of Medical Supply Technician. The VA cited the Freedom of Information Act (FOIA) (5 U.S.C. § 552) and Privacy Act of 1974 (Privacy Act) (5 U.S.C. §552a) as the bases for these revisions to the report produced in response to 5 U.S.C. § 1213. 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). OSC also objects to the VA's use of the Privacy Act to remove the names of the employee on the basis that the application of the Privacy Act in this manner is overly broad.