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OFFICE OF INSPECTOR GENERAL

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BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

HEARING ON

**"REUSABLE MEDICAL EQUIPMENT: CONTINUING TO EXAMINE VHA'S STERILE
PROCESSING PROBLEMS"**

September 5, 2018

Mr. Chairman, Ranking Member Kuster, and members of the Subcommittee, thank you for the opportunity to discuss the Office of Inspector General's (OIG's) oversight of VA facilities' Sterile Processing Services (SPS) and how VA has responded to our recommendations. High-quality sterile processing of reusable instruments and equipment is critical to patient safety, yet has traditionally been difficult for VA to consistently deliver.

BACKGROUND

Over the past decade, the OIG has issued significant findings and recommendations for corrective action related to sterile processing of Reusable Medical Equipment (RME). As highlighted in our March 2018 report on *Critical Deficiencies at the Washington, DC VA Medical Center* (DC Report), there is still cause for concern regarding the management of sterile processing operations and VA's ability to ensure consistent compliance with quality standards across its medical facilities. The DC Report underscores the ongoing need for VA leaders to respond aggressively to reports of management failures within individual facilities' Sterile Processing Services and other hospital business lines that have a direct impact on patient care. Just as consequential, VA must take appropriate proactive steps to ensure these processes are properly carried out by adequately trained professionals whose work and qualifications are being consistently and carefully monitored.

Ensuring that Sterile Processing Services are functioning properly is of critical importance. To advance both patient safety and sound financial management, RME must be reprocessed by individuals with the required competencies, according to manufacturers' instructions and related procedures, and then inventoried, secured, and maintained in clean conditions. Proper sterile processing and storage of RME is essential to preventing contamination and patient infections, as well as product deterioration. The OIG has reported instances in which improper sterile processing has resulted in canceled surgeries and delays in procedures, inefficiency due to repeat processing of RME, and increased risk of patient harm.

OIG OVERSIGHT

The OIG has provided oversight of Sterile Processing Services primarily through two types of inspections or reviews. First, we have conducted reviews and published individual reports in response to specific allegations of problems with sterile processing of RME, usually through complaints received by the OIG Hotline. The second line of reporting results from our Comprehensive Healthcare Inspections Program (CHIP) in which OIG staff examine sterile processing as part of recurring routine inspections of VA medical centers (VAMCs).

As an example of specific allegations, in 2009, OIG reported on the Veterans Health Administration's (VHA) difficulty reprocessing endoscopes and concluded that,¹

“Facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Reprocessing of endoscopes requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care. The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure.”

In 2010, we reported on similar issues in Puerto Rico where RME was not properly sent for reprocessing.² In addition to the RME issues that involve surgical service, the OIG has reported on instrument reprocessing issues with dental equipment, which is not directly under the control of Sterile Processing Services in all facilities.³

¹ *Healthcare Inspection Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities*, June 16, 2009.

² *Healthcare Inspection Patient Safety Issues VA Caribbean Healthcare System San Juan, Puerto Rico*, March 6, 2010.

³ *Healthcare Inspection Reprocessing of Dental Instruments John Cochran Division of the St. Louis VA Medical Center St. Louis, Missouri*, March 7, 2011; *Oversight Review of Dental Clinic Issues Dayton VA Medical Center Dayton, Ohio*, April 25, 2011; *Healthcare Inspection—Review of Improper Dental Infection Control Practices and Administrative Action*, Tomah VA Medical Center, Tomah, Wisconsin, September 7, 2017.

As for CHIP reviews, previously known as the Combined Assessment Program (CAP) reviews, the OIG performs recurring inspections of all VAMCs in which we assess a wide range of hospital functions and performance areas. In the 2009–2010 CAP cycle, sterile processing was one of the areas reviewed. In a 2010 roll-up report of data and trends from completed CAP reviews, the OIG provided recommendations for system-wide improvements to Sterile Processing Services. The OIG reported the following:

“We identified six areas that needed improvement. We recommended that the Under Secretary for Health, in conjunction with Veterans Integrated Service Network and facility senior managers, ensures that: (1) standard operating procedures (SOPs) be current, consistent with manufacturers’ instructions, and located within the reprocessing areas; (2) employees consistently follow SOPs, supervisors monitor compliance, and annual training and competency assessments be completed and documented; (3) flash sterilization be used only in emergent situations, supervisors monitor compliance, and managers assess and document annual competencies for employees who perform flash sterilization; (4) appropriate personal protective equipment be donned before entering and worn in decontamination areas; (5) ventilation systems be inspected and filters changed quarterly in all reprocessing areas and that temperature and humidity levels be monitored and maintained within acceptable ranges in sterile storage areas; and (6) processes for consistent internal oversight of RME activities be established to ensure senior management involvement.”

Altogether, the above OIG reports highlighted the need for proper equipment sterilization throughout each medical center. They also demonstrated that VA did not employ business practice standards that were consistently enforced in all areas of the medical centers that use and reprocess medical equipment.

VA RESPONSE

In VA’s response to our findings, there was recognition that beyond the specific issues we identified, there were important organizational challenges that needed to be addressed to ensure consistent and proper reprocessing of surgical equipment. In their response to our 2009 endoscopy report, VA stated,⁴

“Additional components that VHA will specifically evaluate and address include organizational structures and systems in order to ensure reusable medical equipment is reprocessed according to manufacturers’ instructions with high reliability, and to document facility compliance with recommended standard operating procedures as well as with

⁴ *Healthcare Inspection Follow-Up Colonoscopy Reprocessing at VA Medical Facilities*, September 17, 2009.

implementation of appropriate responses to alerts and directives impacting reprocessing. VHA will take several measures to ensure this:

- A. VHA will implement systems to ensure that all individuals engaged in reprocessing reusable medical equipment will have device-specific competencies documented and demonstrated at a minimum on an annual basis.*
- B. VHA will implement measures to ensure that device and procedure specific standard operating procedures (SOPs) are uniformly available, are updated as required, and are reviewed at least annually.*
- C. And ensure that robust quality control is implemented and appropriately documented in all VHA facilities where reprocessing occurs.*
- D. VHA will standardize equipment at the facility level where ever possible to ensure uniformity in the setup, use and reprocessing of equipment.*
- E. VHA will negotiate national contracts to ensure standardization of equipment and leverage its ability to maximize added value from the vendors, including support of maintenance, repair and training.”*

VA also took the significant step of reorganizing the management of Sterile Processing Services to fall under nursing staff supervision.

The progress that VA made was seen in the 2016 CAP review cycle, when the OIG again included a section focused on sterile processing. The OIG team reviewed facility policies, procedures and guidelines for (1) reprocessing RME, (2) training and demonstrating competencies for employees who reprocess RME, and (3) quality control measures for testing bioburdens in endoscopes. In addition, the review tested whether the manufacturer’s instructions for proper sterile processing, local SOPs, and quality control measures were in place for the reprocessing of selected endoscopes at central and peripheral areas within the VAMC. The majority of medical centers reviewed during the 2016 CAP inspection cycle scored above 90 percent in the sterile processing section. VA also demonstrated that policies were in place to review the quality of reprocessing of individual scopes if quality assurance testing indicated the scope was not reprocessed correctly.⁵

The results of the 2016 reviews indicate that many facility leaders were focused on ensuring sterile processing of RME was being correctly performed and demonstrated marked improvement from previous reviews. In support of these findings, the OIG is

⁵ Data pulled from individual CAP reviews from Fiscal Year 2016 cycle.

aware of numerous instances at VAMCs where sterile processing errors were made and the proper corrective actions were taken or the operating room was closed until further evaluation of instrument status could be obtained.⁶ Although shutdowns should clearly be avoided, it is important to be supportive of facilities that recognize a problem and take proper measures to ensure patient safety. In recent years, the OIG has engaged in numerous informal discussions with VA leaders when there have been reports or evidence of a possible sterilization problem at a medical center. In these instances, we have found overall that appropriate prompt actions have been taken by VA to ensure sterile processing errors do not result in more serious adverse outcomes for patients.

CRITICAL DEFICIENCIES AT THE WASHINGTON DC VAMC

VA's improvements in sterile processing make the findings in our report, *Critical Deficiencies at the Washington, DC VA Medical Center*, all the more startling.⁷ The OIG detailed multiple and extensive deficiencies within the Washington, DC VAMC's Sterile Processing Services that impeded healthcare providers' efforts to deliver quality patient care, included the following:

- Problems in the sterile processing of instruments, such as discolored or broken instruments reaching clinical areas; incomplete surgical trays in the operating room; improper tracking and reprocessing procedures for loaner instruments; missing or expired sterile processing supplies; failure to follow reprocessing instructions; and not separating clean and dirty items in satellite reprocessing areas
- An ineffective quality assurance program to ensure that instruments were cleaned appropriately prior to being returned to a clinical area
- No reliable way for ensuring that instrument sets sent back to clinical areas were complete and ready for use
- Some clean/sterile storerooms did not meet selected infection prevention criteria and/or selected cleanliness criteria
- Multiple problems with competencies for the technicians responsible for sterilizing instruments and equipment, including expired or undated competencies, lack of documentation regarding required training, and competencies not consistently updated to keep pace with manufacturer's issuance of instructions

DC VAMC personnel often attributed deficiencies in Sterile Processing Services to chronic understaffing. The OIG confirmed that Sterile Processing Services had

⁶ *Healthcare Inspection – Delayed Access to Primary Care, Contaminated Reusable Medical Equipment, and Follow-Up of Registered Nurse Staffing Concerns, Southern Arizona VA Health Care System, Tucson, Arizona, September 26, 2017.*

⁷ *Critical Deficiencies at the Washington DC VAMC, March 7, 2018.*

experienced historically high vacancy rates. A number of factors contributed to these rates, including a failure to maintain accurate data on the number of authorized positions throughout the medical center; the Resource Management Committee not performing its duties in accordance with policy; and HR not completing hiring actions appropriately.

The OIG also determined that high turnover rates in HR leadership may have contributed to the failure to resolve staffing issues. VA has reported progress in hiring, but vacancy rates for Sterile Processing Services staff are still high at the medical center. During our DC review, VHA leaders reported that they have experienced difficulties in recruiting qualified SPS staff nationwide, in part because of a relatively low salary structure. The fact that many VAMCs continue to provide high-quality Sterile Processing Services suggests that staffing issues alone do not necessarily result in deficiencies like those found at the DC VAMC.

Additionally, it is important to note that the problems identified in the DC Report were not new. It is clear that information and documentation outlining some, if not most, of the sterile processing failings in the medical center reached responsible officials as early as 2013. That includes the DC VAMC leadership, the Veteran Integrated Service Network (VISN) 5 leaders, and VHA Central Office.⁸ However, actions taken by leadership did not effectively remediate the conditions. Overall, the DC Report highlights the negative impacts resulting from a lack of leadership attention placed upon key business practices and logistics.

During the DC VAMC review process, we noted some real-time improvements in the cleanliness of storage rooms. The medical center had entered into a contract with a commercial cleaning service in June 2017 to supplement the medical center Environmental Management Services staff. Additionally, as of September 2017, the Acting Human Resources Director reported to the OIG that 138 of 147 authorized EMS positions were filled. We have conducted a follow-up review of the DC VAMC and will be reporting our findings in the near future.

CONCLUSION

Although the findings and recommendations in the DC Report focus on issues in sterile processing at that facility, VHA leadership at all levels could use the findings as a checklist to ensure properly functioning Sterile Processing Services at all VAMCs. The DC Report is about the breakdown of systems and leadership at multiple levels that other VAMCs should be cautioned to avoid or quickly redress.

The OIG's ongoing oversight and communication with VA leaders indicates that some individual facilities have made important strides in how sterile processing is managed.

⁸ VISN 5, VA Capitol Health Care Network, has managerial oversight responsibility over the Washington, DC VAMC.

Yet reports like the one on the DC VAMC makes clear that these problems still resurface in individual facilities, due in part to both the complexity of the processes and the lack of adequate internal controls to provide assurance that sterile processing is meeting essential quality standards. Staffing may also be an ongoing challenge in addressing sterile processing problems. Finally, VA must have effective leaders who understand the critical importance of close oversight of nonclinical services that affect patient care within medical centers to continue its improvement efforts. Leaders at all VA facilities must take appropriate proactive steps and have reactive measures in place to address sterile processing concerns. Failure to do so puts at risk the safety and quality of care delivered to veterans.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions you or other members of the Subcommittee may have.