United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

For Release on Delivery
Expected at 10:00 a.m ET
Wednesday, September 5, 2018

VA HEALTH CARE

Improvements in Oversight Needed for Reusable Medical Equipment

Statement of Sharon Silas, Acting Director, Health Care

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee:

I am pleased to be here today to discuss the use of reusable medical equipment (RME) in the Department of Veterans Affairs (VA). As you know, VA's Veterans Health Administration (VHA) operates one of the largest health care delivery systems in the nation, serving over 9 million enrolled veterans. In providing health care services to veterans, VA medical centers use RME, such as endoscopes and surgical instruments, which must be reprocessed—that is, cleaned, disinfected, or sterilized—between uses.[1] The proper reprocessing of surgical instruments and other RME used in medical procedures is critical for ensuring veterans' access to safe care. Accordingly, VHA policy establishes requirements VA medical centers must follow when reprocessing RME to help ensure the safety of veterans who receive care at its facilities.

Nevertheless, VHA has had ongoing challenges related to properly reprocessing RME. For example, in 2011 we found that VHA had not provided sufficient guidance to VA medical center staff operating the Sterile Processing Services (SPS) programs to ensure that staff were reprocessing RME correctly, which posed potential safety risks to veterans.[2] In 2016, the VHA Office of the Medical Inspector reviewed and corroborated allegations that the SPS department at one VA medical center failed to provide surgeons with RME free of bioburden, debris, or both.[3] Further, in March 2018, the VA Office of Inspector General

[1]An endoscope is an instrument used for direct visual inspection of hollow organs or body cavities.

[2]The VA medical center SPS programs consist of the SPS department, which has primary responsibility for reprocessing RME, and other areas such as dental clinics, where certain reprocessing functions occur. See GAO, *VA Health Care: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety,* GAO-11-391 (Washington, D.C.: May 3, 2011). We recommended that VA develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VA medical centers and that VA hold VA medical centers accountable for implementing device-specific training for all of these RME. VA concurred with this recommendation, and, in November 2012, stated that over 1,200 employees had been certified by a professional organization dedicated to the education and certification of SPS employees. In addition, in March 2016, VA implemented a policy which requires, among other things, standardized training for reprocessing RME and oversight of reprocessing activities.

[3]Bioburden is a measure of an object's microorganism contamination. See Department of Veterans Affairs, *Department of Veterans Affairs Cincinnati Veterans Affairs Medical Center Cincinnati, Ohio, Veterans Integrated Service Network 10,* TRIM 2016-D-1082 (Washington, D.C.: May 8, 2016).

reported on problems at another VA medical center including delayed and cancelled procedures due to the fact that the necessary RME had not been properly reprocessed and were therefore unavailable.[4]

My testimony today summarizes the findings from our August 2018 report that analyzed VA's oversight of reusable medical equipment.[5] Accordingly, this testimony addresses

1. VHA's oversight of VA medical centers' adherence to RME policies, and
2. challenges VA medical centers face in operating their SPS programs and efforts VHA has taken to address these challenges.

As part of my testimony, I will highlight the three recommendations we made to VA to improve its oversight of RME and ensure access to safe care for veterans. VA concurred with all three of the recommendations and said it would take actions to implement them.

To conduct the work for our August 2018 report, we reviewed VHA RME policy as well as other documents such as VHA Directive 1116(2), which describes RME policy requirements and instructions for how inspections of VA medical centers' adherence to these requirements should be conducted.[6] We also reviewed VHA summary data on inspections of VA medical centers conducted by their respective Veterans Integrated Service Networks (VISN) in fiscal year 2017.[7] We reviewed the full inspection reports provided by the VISNs for inspections the VISNs had conducted in fiscal year 2017, but for which VHA did not have a record, and identified information about nonadherence to RME policy requirements. In addition, we interviewed VHA officials, officials from all 18 VISNs, and officials from four VA medical centers selected for our

[4]See Department of Veterans Affairs, Office of Inspector General, Veterans Health Administration, *Critical Deficiencies at the Washington DC VA Medical Center,* Report #17-02644-130 (Washington, D.C.: Mar. 7, 2018).

[5]See GAO, *VA Health Care: Improved Oversight Needed for Reusable Medical Equipment,* GAO-18-474, (Washington, D.C.: Aug. 3, 2018).

[6]See VHA Directive 1116(2), *Sterile Processing Services (SPS)* (Washington, D.C.: Mar. 23, 2016). See Department of Veterans Affairs, Deputy Undersecretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs* (Washington, D.C.: June 26, 2017).

[7]VISNs are responsible for ensuring adherence to VHA's policies among the VA medical centers within their region.

review.[8] As part of our review, we assessed VHA's oversight efforts and its efforts to address any identified RME-related challenges in the context of federal standards for internal control.[9] Further details regarding the scope and methodology of our work are included in our August 2018 report. The work on which this statement is based was performed in accordance with generally accepted government auditing standards.

VHA's Oversight Does Not Provide Reasonable Assurance That VA Medical Centers Are Following RME Policies

In our August 2018 report, we found that VHA had not ensured that it has complete information from the annual inspections VISNs conduct. VISNs are required to conduct annual inspections at each VA medical center within their VISN and to report their inspection results to VHA. These inspections are a key oversight tool providing the most current information on adherence to RME policies VA-wide, as VHA does not inspect every VA medical center each year. VHA's lack of complete information from inspection results is inconsistent with standards for internal control in the federal government regarding monitoring and information that state management should establish and operate monitoring activities and use quality information to achieve the entity's objective.[10] Without complete information from these inspections, VHA cannot reasonably ensure that VA medical centers are following RME policies intended to ensure veterans are receiving safe care.

For fiscal year 2017, we determined that VHA was missing 39—or more than one-quarter—of the required VISN inspection reports.[11] VISN

[8]We selected the four VA medical centers to achieve geographic and medical center complexity variation and the highest and lowest performance regarding operating room lag time. VHA assigns each VA medical center to one of five complexity groups based on patient population served, clinical services offered, education and research complexity, and administrative complexity. Operating room lag time data captures the time elapsed from one patient leaving and the next patient entering the operating room; lag time can be attributed to RME not being available, among other factors. The four VA medical centers we selected were located in Chicago, IL; Erie, PA; Fort Meade, SD; and Little Rock, AR. We were not able to speak with the Chief of SPS at the Chicago Jesse-Brown VA medical center; as such, some of our reported results are for three VA medical centers.

[9]See GAO, Standards for Internal Control in the Federal Government, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

[10]See GAO-14-704G.

[11]VISNs were able to provide GAO with evidence that they had conducted 27 of the 39 missing inspections.

officials suggested several reasons for the missing reports. For example, an official from one VISN provided evidence that the VISN had conducted almost all of its inspections, but told us the VISN did not submit reports to VHA because it has yet to receive information from VHA regarding VISN inspection outcomes, common findings across VISNs, or best practices and therefore the VISN sees no value in submitting the reports. A VHA official told us the office had not been aware that it did not have all of the required VISN inspection reports because it has largely relied on the VISNs to monitor inspections since VHA does not have sufficient resources to do so itself.

We also found in our report that VHA does not consistently share information, particularly inspection results, with VISNs and VA medical centers, and that VISNs and VA medical centers would like more of this information. Specifically, about two-thirds of the VISN and VA medical center officials we interviewed told us that sharing information on the common issues identified by VA medical center inspections as well as potential solutions developed to address these issues would allow the VA medical centers to be proactive in strengthening their adherence to RME policies and ensuring patient safety. For example, one VA medical center official we interviewed told us that there were problems with equipment designed to sterilize heat- and moisture- sensitive devices, and that seeing how other VA medical centers addressed the problem would be helpful. Further, officials from some VISNs we interviewed said VHA cited their VA medical centers for issues that had been found at other facilities and that, had they been aware of the issue beforehand, they could have corrected or improved their processes for adhering to RME policies.

When asked about sharing inspection results and other information, VHA Central Office officials told us the office does not analyze or share VISN inspections information due to inadequate resources. More specifically, one VHA official told us that the office does create an internal report of common issues identified through the third of VA medical centers it inspects each year, but does not share this report with VISNs and VA medical centers because the office lacks the resources needed to prepare reports that are detailed enough to be correctly understood by the VISN and VA medical center recipients. According to this official, VHA has occasionally shared information regarding common inspection issues through newsletters, national calls, and trainings. However, VHA officials we interviewed at 8 of the 18 VISNs and 1 of the 4 VA medical centers we reviewed said that they rarely or never received such information. For example, officials from one VISN told us that they recall just one or two instances where VHA sent a summary of the top five RME-related issues

found during VHA inspections. Insufficient sharing of information is inconsistent with standards for internal control in the federal government regarding communication, which state that management should internally communicate the necessary quality information to achieve the entity's objectives.[12] Until this sharing becomes a regular practice, VHA is missing an opportunity to help ensure adherence to its RME policies, which are intended to ensure that veterans receive safe care.

Based on our findings, in our August 2018 report we recommended that VA take steps to ensure that all RME inspections are being conducted and the results of those inspections are reported to VHA as required. We also recommended that VA consistently analyze and share top common RME inspection findings and possible solutions with VISNs and VA medical centers. VA concurred with these recommendations and said it would establish an oversight process for reviewing and monitoring findings from RME inspections and for reporting this information to VHA leadership. Further, VA noted that VHA will analyze data from RME inspections and share findings and possible solutions with VISNs and VA medical centers via a written briefing.

VA Medical Centers Reported Facing Challenges Related to RME Policies and Workforce Needs, but VHA Has Not Sufficiently Addressed These Challenges

We also found in our August 2018 report that the top challenges VA medical centers face in operating their SPS programs were related to meeting certain RME policy requirements and challenges addressing SPS workforce needs. Regarding the challenges VA medical centers face in meeting RME policy requirements, the majority of the 18 VISN and four selected VA medical center officials interviewed reported experiencing challenges adhering to two requirements from VHA's 2016 Directive 1116(2).

- **Climate control monitoring requirement.** According to officials from 16 VISNs and two VA medical centers, meeting the climate control monitoring requirement related to humidity and airflow in facility areas where RME is reprocessed and stored is a challenge for some, if not

[12]See GAO-14-704G.

all, of their VA medical centers, particularly older VA medical centers that lack proper ventilation systems.[13]

- **Reprocessing transportation deadline requirement.** Officials from 16 VISNs and two VA medical centers reported that meeting the reprocessing transportation deadline was challenging for their VA medical centers. They said this was particularly challenging for VA medical centers that must transport their RME to another facility for cleaning, such as community based outpatient clinics in rural areas that must transport their RME to their VA medical center's SPS department.[14] Under the requirement, used RME must be transported to the location where it will be reprocessed within 4 hours of use to prevent bioburden or debris from drying on the instrument and causing reprocessing challenges.

In a report we issued in September 2017 examining VA's policy management practices, we recommended that VHA establish a mechanism through which program offices could systematically obtain feedback from VISN and VA medical center officials after the implementation of new national policies.[15] The more recent findings of our August 2018 report provide further evidence of the need for VA to address that recommendation.

Regarding the challenges VA medical centers face in meeting SPS workforce needs, almost all of the 18 VISN officials and officials from the three selected VA medical centers we interviewed reported experiencing challenges related to lengthy hiring timeframes, the need for consistent overtime practices, and limited pay and opportunities for professional growth. According to these officials, such challenges make it difficult for SPS programs to maintain sufficient staffing levels.

[13]Under the climate control monitoring requirement, airflow needs to be carefully controlled in areas where RME is reprocessed and stored to minimize movement of air from dirty areas to clean areas (e.g., areas where used instruments are brought to be reprocessed and areas where unused instruments are stored before usage). Also, humidity must be monitored in the areas RME is reprocessed and stored so that humidity levels do not exceed certain thresholds.

[14]Under the reprocessing deadline requirement, all used RME must be transported to the location where it will be reprocessed within 4 hours (or 12 hours for offsite facilities if a specific pre-cleaning spray is used, per a VHA memorandum issued on June 1, 2016).

[15]VHA agreed with our recommendation; however, as of March 2018 VHA had not implemented it. GAO, *VA Health Care: Additional Actions Could Further Improve Policy Management,* GAO-17-748 (Washington, D.C.: Sept. 22, 2017).

- **Lengthy hiring timeframes.** Officials from 14 VISNs and three VA medical centers reported that the lengthy hiring process for SPS staff creates challenges in maintaining a sufficient SPS workforce. For example, officials from one VISN estimated that it can take 3 to 4 months on average to hire a new SPS staff member.
- **Need for overtime.** Officials from 16 VISNs and two VA medical centers reported that needing SPS staff to work overtime is a challenge. Further, officials from one VISN told us that their VA medical center had used overtime to meet increased workload demands required to implement VHA's RME policies. One official we interviewed noted that the overtime has led to dissatisfaction and retention issues among SPS staff.
- **Limited pay and opportunities for professional growth.** Officials identified limited pay and lack of opportunities for professional growth as the biggest SPS workforce challenge.[16] These officials stated that the relatively low maximum allowable pay discourages staff from accepting or staying in SPS positions and the current pay grade does not create a career path for SPS medical supply technicians to grow within the SPS department. VHA officials told us that a proposed increase in the pay grade for SPS staff has been drafted; however, the officials do not know when or if it will be made effective. Further, according to VHA officials with knowledge of the proposed changes, the changes could still be insufficient to recruit and retain SPS staff with the necessary skills and experience.

While VHA is aware of these workforce challenges cited by VISN and VA medical center officials, it has not studied SPS staffing issues at VA medical centers. VHA officials told us that VHA is considering studying its SPS workforce. However, the agency has not announced a plan or a timeframe for doing so. Until the study is conducted and actions are taken based on the study, as appropriate, VHA will not have addressed a potential risk to its SPS programs. This is inconsistent with standards for internal control in the federal government for risk assessment, which state that management should identify, analyze, and respond to risks related to achieving defined objectives.[17] Without examining SPS workforce needs, and taking action based on this assessment, as appropriate, VHA lacks

[16]In our review, officials from all 18 VISNs and three VA medical centers reported experiencing challenges with relatively low pay. Officials from 14 VISNs and 1 VA medical center reported experiencing challenges with professional growth for SPS staff.

[17]See GAO-14-704G.

reasonable assurance that its approach to SPS staffing helps ensure veterans' access to care and safety.

Based on our findings, we recommended in our August 2018 report that VA assess its SPS workforce needs, and take action based on this assessment, as appropriate. VA concurred with this recommendation and said that VHA has an interdisciplinary work group that has identified actions it can take to address SPS workforce needs.

Chairman Bergman, Ranking Member Kuster, and Members of the Subcommittee, this concludes my statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Sharon Silas at (202) 512-7114 or silass@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. In addition to the contact named above, key contributors to this statement were Karin Wallestad (Assistant Director), Teresa Tam (Analyst-in-Charge), Kenisha Cantrell, Krister Friday, and Michael Zose.