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VA HEALTH CARE

Weaknesses in Policies and Oversight Governing Medical Equipment Pose Risks to Veterans' Safety

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G A O

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Chairman Miller, Ranking Member Filner, and Members of the Committee:

I am pleased to be here today as you discuss patient safety incidents at Department of Veterans Affairs (VA) medical centers and potential strategies to address the underlying causes of those incidents. VA operates one of the largest integrated health care delivery systems in the United States, providing care to over 5.5 million veterans annually. Organized into 21 Veterans Integrated Service Networks (VISN), VA's health care system includes 153 VA medical centers (VAMC) nationwide that offer a variety of outpatient, residential, and inpatient services.¹ In providing health care services to veterans, clinicians at VAMCs use reusable medical equipment (RME), which is designed to be reused for multiple patients and includes such equipment as endoscopes² and some surgical and dental instruments. Because RME is used when providing care to multiple veterans, this equipment must be reprocessed—that is, cleaned and disinfected or sterilized—between uses. VA has established requirements for VAMCs to follow when reprocessing RME,³ which are designed, in part, to help ensure the safety of the veterans who receive care at VAMCs.

My testimony today, based on our May 2011 report,⁴ which is being released today, examines issues related to veterans' safety, including (1) selected reprocessing requirements established in VA policies, based on their relevance to patient safety incidents and (2) VA's oversight of VAMCs' compliance with these selected requirements.

¹The management of VAMCs is decentralized to 21 VISNs.

²An endoscope is a device with a light attached that is used to look inside a body cavity or organ.

³VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements* (Aug. 16, 2002); VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities* (Feb. 9, 2009); and VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements* (June 26, 2009).

⁴See 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 2011).

To examine VA reprocessing requirements, we reviewed relevant VA policies and from these policies, we judgmentally selected the following two types of reprocessing requirements that we determined were relevant to patient safety incidents that were identified at certain VAMCs.⁵

Training requirements. To ensure that RME is reprocessed in accordance with manufacturers' guidelines, VA requires that each VAMC develop device-specific training for reprocessing RME. To develop this training, VA requires VAMCs to create device-specific standard operating procedures (SOP), which provide step-by-step instructions for reprocessing. VA also requires VAMCs to assess staff annually on their competence to reprocess RME in accordance with these SOPs.

Operational requirements. To ensure that reprocessing activities are performed safely and that RME is reprocessed correctly, VA policies establish operational requirements for VAMCs, which include that VAMC staff must monitor sterilizers to ensure that they are functioning properly, use personal protective equipment when performing reprocessing activities, and segregate dirty and clean RME.

After selecting these requirements for our review, we judgmentally selected six VAMCs from the following locations to visit: Albany, New York; Cheyenne, Wyoming; Detroit, Michigan; Miami, Florida; Palo Alto, California; and St. Louis, Missouri. These VAMCs represent different surgical complexity groups,⁶ sizes of veteran populations served, and geographic regions.⁷ At these six VAMCs, we examined the adequacy of the selected reprocessing requirements to help the facilities ensure the safety of veterans who received care at these facilities. To do this, we examined how the selected requirements were implemented and whether or to what extent these requirements directly or indirectly created a

⁵We reviewed applicable VA policies, including VHA Directive 2009-031, *Improving Safety in the Use of Reusable Medical Equipment Through Standardization of Organizational Structure and Reprocessing Requirements*; VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*; and VA Handbook 7176, *Supply, Processing, and Distribution (SPD) Operational Requirements*.

⁶VA assigns each VAMC a complexity score between 1 and 3, with level 1 being the most complex, using a facility complexity model. That model uses multiple variables to measure facility complexity arrayed along four categories, namely patient population served, clinical services offered, education and research complexity, and administrative complexity.

⁷Each of the six VAMCs we visited is located within a different VISN.

potential risk to veterans' safety. We reviewed applicable VAMC committee meeting minutes⁸ and other documentation on the implementation of these requirements. We also interviewed VAMC officials who were responsible for implementing the selected requirements to determine whether these requirements are adequate to help ensure veterans' safety.

To examine VA's oversight of VAMCs' compliance with the selected reprocessing requirements, we reviewed VA's oversight of these requirements and evaluated whether this oversight provides VA with adequate information to identify and address noncompliance. As part of this review, we assessed VA's oversight in the context of federal standards for internal control for monitoring.⁹ The internal control for monitoring refers to an agency's ability to assure that ongoing review and supervision activities are conducted, with the scope and frequency depending on the assessment of risks; deficiencies are communicated to at least one higher level of management; and actions are taken in response to findings or recommendations within established timelines. We interviewed officials responsible for overseeing VAMCs' compliance with the requirements we selected for review from VA headquarters, VA's Office of Inspector General (OIG), and six VISNs that are responsible for overseeing compliance with the requirements we selected for review at the VAMCs we visited. In addition, we obtained and reviewed relevant documents regarding VA oversight, including internal reports, VAMCs' plans to correct problems identified through oversight activities, and policy memorandums.

We conducted this performance audit from March 2010 to May 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁸We reviewed minutes from the following committees: commodity standards, equipment, medical executive, infection control, and RME.

⁹See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999) and GAO, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

In summary, we found that the VA reprocessing requirements we selected for review are inadequate to help ensure the safety of veterans who receive care at VAMCs. Although VA requires VAMCs to develop device-specific training for staff on how to correctly reprocess RME, it has not specified the types of RME for which this training is required. Furthermore, VA has provided conflicting guidance to VAMCs on how to develop device-specific training on reprocessing RME.¹⁰ This lack of clarity may have contributed to delays in developing the required training. Without appropriate training on reprocessing, VAMC staff may not be reprocessing RME correctly, which poses potential risks to veterans' safety. VA headquarters officials told us that VA has plans to develop training for certain RME, but VA lacks a timeline for developing this training.

We also found that despite changes to improve VA's oversight of VAMCs' compliance with selected reprocessing requirements, weaknesses still exist. These weaknesses render VA unable to systematically identify and address noncompliance with the requirements, which poses potential risks to the safety of veterans. Although VA headquarters receives information from the VISNs on any noncompliance they identify, as well as VAMCs' corrective action plans to address this noncompliance, VA headquarters does not analyze this information to inform its oversight. According to VA headquarters officials, VA intends to develop a plan for analyzing this information to systematically identify areas of noncompliance that occur frequently, pose high risks to veterans' safety, or have not been addressed across all VAMCs.

To address the inadequacies we identified in selected VA reprocessing requirements, GAO recommends that VA develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VAMCs and hold VAMCs accountable for implementing this training. To address the weaknesses in VA's oversight of VAMCs' compliance with selected requirements, GAO recommends that VA use information on noncompliance identified by the VISNs and information on VAMCs' corrective action plans to identify areas of noncompliance across all 153 VAMCs and take action to improve compliance in those areas.

¹⁰According to VA headquarters officials, certain RME are difficult to reprocess because they need to be fully disassembled in order to be reprocessed correctly, so developing device-specific training for reprocessing these items is important to help ensure veterans' safety.

Selected VA Reprocessing Requirements Are Inadequate to Help Ensure Veterans' Safety

We found that the VA reprocessing requirements we selected for review are inadequate to help ensure veterans' safety.

Lack of specificity about types of RME that require device-specific training. The VA reprocessing requirements we reviewed do not specify the types of RME for which VAMCs must develop device-specific training. This inadequacy has caused confusion among VAMCs and contributed to inconsistent implementation of training for reprocessing. While VA headquarters officials told us that the training requirement is intended to apply to RME classified as critical—such as surgical instruments—and semi-critical—such as certain endoscopes,¹¹ officials from five of the six VAMCs we visited told us that they were unclear about the RME for which they were required to develop device-specific training.

Officials at one VAMC we visited told us that they did not develop all of the required reprocessing training for critical RME—such as surgical instruments—because they did not understand that they were required to do so. Officials at another VAMC we visited also told us that they had begun to develop device-specific training for reprocessing non-critical RME, such as wheelchairs, even though they had not yet fully completed device-specific training for more critical RME. Because these two VAMCs had not developed the appropriate device-specific training for reprocessing critical and semi-critical RME, staff at these VAMCs may not have been reprocessing all RME properly, which potentially put the safety of veterans receiving care at these facilities at risk.

Conflicting guidance on the development of RME reprocessing training. While VA requires VAMCs to develop device-specific training on reprocessing RME, VA headquarters officials provided VAMCs with conflicting guidance on how they should develop this training. For example, officials at three VAMCs we visited told us that certain VA headquarters or VISN officials stated that this device-specific training should very closely match manufacturer guidelines—in one case verbatim—while other VA headquarters or VISN officials stated that this

¹¹RME is generally categorized into critical, semi-critical, or non-critical items based on the degree of risk for infection involved in use of the item. Critical items, such as surgical instruments, are those that enter sterile tissue or the vascular system and require sterilization because they confer a high risk of infection. Semi-critical items, such as certain endoscopes, are those that contact mucous membranes or non-intact skin and minimally require high-level disinfection. Non-critical items, such as wheelchairs, are those that come into contact with intact skin and may be cleaned with low-level disinfectants.

training should be written in a way that could be easily understood by the personnel responsible for reprocessing RME. This distinction is important, since VAMC officials told us that some of the staff responsible for reprocessing RME may have difficulty following the more technical manufacturers' guidelines.¹² In part because of VA's conflicting guidance, VAMC officials told us that they had difficulty developing the required device-specific training and had to rewrite the training materials multiple times for RME at their facilities. Officials at five of the six VAMCs also told us that developing the device-specific training for reprocessing RME was both time consuming and resource intensive.

VA's lack of specificity and conflicting guidance regarding its requirement to develop device-specific training for reprocessing RME may have contributed to delays in developing this training at several of the VAMCs we visited. Officials from three of the six VAMCs told us that they had not completed the development of device-specific training for RME since VA established the training requirement in July 2009. As of October 2010, 15 months after VA issued the policy containing this requirement, officials at one of the VAMCs we visited told us that device-specific training on reprocessing had not been developed for about 80 percent of the critical and semi-critical RME in use at their facility.

VA headquarters officials told us that they are aware of the lack of specificity and conflicting guidance provided to VAMCs regarding the development of training for reprocessing RME and were also aware of inefficiencies resulting from each VAMC developing its own training for reprocessing types of RME that are used in multiple VAMCs. In response, VA headquarters officials told us that they have made available to all VAMCs a database of standardized device-specific training developed by RME manufacturers for approximately 1,000 types of RME and plan to require VAMCs to implement this training by June 2011. The officials also told us that VA headquarters is planning to develop device-specific training available to all VAMCs for certain critical and semi-critical RME for which RME manufacturers have not developed this training, such as dental instruments. However, as of February 2011, VA headquarters had not

¹²VA officials stated that manufacturer guidelines for reprocessing RME may be technically complex and may include steps that staff at VAMCs are unable to follow. For example, these officials stated that guidelines from RME manufacturers may require the use of a specific disinfectant that is not available in the United States. The Food and Drug Administration has responsibility for overseeing RME, including the guidelines written by manufacturers for reprocessing these items.

completed the development of device-specific training for these RME and has not established plans or corresponding timelines for doing so.

Despite Changes Intended to Improve VA's Oversight of VAMCs' Compliance with Selected Reprocessing Requirements, Weaknesses Continue to Exist

We found that VA recently made changes to its oversight of VAMCs' compliance with selected reprocessing requirements; however, this oversight continues to have weaknesses. Beginning in fiscal year 2011, VA headquarters directed VISNs to make three changes intended to improve its oversight of these reprocessing requirements at VAMCs.¹³

- VA headquarters recently required VISNs to increase the frequency of site visits to VAMCs—from one to three unannounced site visits per year—as a way to more quickly identify and address areas of noncompliance with selected VA reprocessing requirements.
- VA headquarters also recently required VISNs to begin using a standardized assessment tool to guide their oversight activities.¹⁴ According to VA headquarters officials, requiring VISNs to use this assessment tool will enable the VISNs to collect consistent information on VAMCs' compliance with VA's reprocessing requirements. Before VA established this requirement, the six VISNs that oversee the VAMCs we visited often used different assessment tools to guide their oversight activities. As a result, they reviewed and collected different types of information on VAMCs' compliance with these requirements.
- VISNs are now required to report to VA headquarters information from their site visits. Specifically, following each unannounced site visit to a VAMC, VISNs are required to provide VA headquarters with information on the facility's noncompliance with VA's reprocessing requirements and VAMCs' corrective action plans to address areas of noncompliance. Prior

¹³VA headquarters generally delegates responsibility for this oversight to the VISNs. In addition to oversight conducted by the VISNs, some entities within VA headquarters conduct oversight of VAMCs' compliance with VA reprocessing requirements, including those we selected for review. Specifically, VA's OIG and Sterile Processing Department conduct site visits to investigate allegations of VAMC noncompliance with VA reprocessing requirements. In addition, since around 2005, VA's System-wide Ongoing Assessment and Review Strategy has included reviews of the selected VA reprocessing requirements as part of broader reviews of VAMC compliance with VA policies in preparation for external accreditation reviews approximately every 3 years. In 2010, VA's OIG also conducted reviews of the selected VA reprocessing requirements as part of broader ongoing reviews of VAMC compliance with VA policies.

¹⁴VA headquarters officials told us that they may refine this assessment tool over time.

to fiscal year 2011, VISNs were generally not required to report this information to VA headquarters.¹⁵

Despite the recent changes, VA's oversight of its reprocessing requirements, including those we selected for review, has weaknesses in the context of the federal internal control for monitoring. Consistent with the internal control for monitoring, we would expect VA to analyze this information to assess the risk of noncompliance and ensure that noncompliance is addressed. However, VA headquarters does not analyze information to identify the extent of noncompliance across all VAMCs, including noncompliance that occurs frequently or poses high risks to veterans' safety. As a result, VA headquarters has not identified the extent of noncompliance across VAMCs with, for example, VA's operational reprocessing requirement that staff use personal protective equipment when performing reprocessing activities, which is key to ensuring that clean RME are not contaminated by coming into contact with soiled hands or clothing. Three of the six VAMCs we visited had instances of noncompliance with this requirement. Similarly, because VA headquarters does not analyze information from VAMCs' corrective action plans to address noncompliance with VA reprocessing requirements, it is unable to confirm, for example, whether VAMCs have addressed noncompliance with its operational reprocessing requirement to separate clean and dirty RME. Two of the six VAMCs we visited had not resolved noncompliance with this requirement and, as a result, are unable to ensure that clean RME does not become contaminated by coming into contact with dirty RME.

VA headquarters officials told us that VA plans to address the weaknesses we identified in its oversight of VAMCs' compliance with reprocessing requirements. Specifically, VA headquarters officials told us that they intend to develop a systematic approach to analyze oversight information to identify areas of noncompliance across all VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been

¹⁵While VISNs were not generally required to report to VA headquarters information on VAMCs' noncompliance with VA's reprocessing requirements, VISNs were required to report to VA headquarters information about noncompliance that may have resulted in harm to veterans. VA headquarters officials told us that following a review of that information and collection of additional information as needed, a panel of experts would determine whether the noncompliance identified in the reviews resulted in risks to veterans' safety and, if so, whether veterans should be notified. See VHA Directive 2008-002, *Disclosure of Adverse Events to Patients* (Washington, D.C.: Jan. 18, 2008).

addressed in a timely manner.¹⁶ While VA has established a timeline for completing these changes, certain VA headquarters officials told us that they are unsure whether this timeline is realistic due to possible delays resulting from VA's ongoing organizational realignment, which had not been completed as of April 6, 2011.¹⁷

In conclusion, weaknesses exist in VA's policies for reprocessing RME that create potential safety risks to veterans. VA's lack of specificity and conflicting guidance for developing device-specific training for reprocessing RME has led to confusion among VAMCs about which types of RME require device-specific training and how VAMCs should develop that training. This confusion has contributed to some VAMCs not developing training for their staff for some critical and semi-critical RME.

Moreover, weaknesses in oversight of VAMCs' compliance with the selected reprocessing requirements do not allow VA to identify and address areas of noncompliance across VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed by VAMCs. Correcting inadequate policies and providing effective oversight of reprocessing requirements consistent with the federal standards for internal control is essential for VA to prevent potentially harmful incidents from occurring.

To help ensure veterans' safety through VA's reprocessing requirements, we are making two recommendations in our report. We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take the following actions:

- Develop and implement an approach for providing standardized training for reprocessing all critical and semi-critical RME to VAMCs. Additionally,

¹⁶VA headquarters officials also told us that a temporary staff member was assigned in March 2011 to begin reviewing some information from VISNs' oversight activities. Specifically, that staff member will be responsible for reviewing whether VAMCs have developed the required device-specific training for reprocessing RME and the extent to which VAMCs are utilizing flash sterilization, a sterilization technique that should be used only in limited circumstances.

¹⁷As part of this realignment, VA headquarters is establishing a new position within the Office of the Deputy Under Secretary for Health for Operations and Management, which will be responsible for overseeing certain departments, including VA headquarters' Sterile Processing Department.

hold VAMCs accountable for implementing device-specific training for all of these RME.

- Use the information on noncompliance identified by the VISNs and information on VAMCs' corrective action plans to identify areas of noncompliance across all 153 VAMCs, including those that occur frequently, pose high risks to veterans' safety, or have not been addressed, and take action to improve compliance in those areas.

In responding to a draft of the report from which this testimony is based, VA concurred with these recommendations.

Chairman Miller, Ranking Member Filner, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Committee may have.

Contacts and Acknowledgments

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