DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

VETERANS HEALTH ADMINISTRATION

Critical Deficiencies at the Washington DC VA Medical Center

REPORT #17-02644-130

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Executive Summary

In March 2017, in response to a confidential complaint, the Department of Veterans Affairs (VA) Office of Inspector General (OIG) deployed a Rapid Response Team to conduct an inspection of the Washington DC VA Medical Center (Medical Center). The OIG took the unusual step of issuing an Interim Report three weeks later that described serious conditions that put both patients and federal government assets at risk.[1] The April 2017 Interim Report identified a number of significant deficiencies at the Medical Center, including the lack of accurate supply and equipment inventories that made it difficult to ensure patient needs were met, generally dirty conditions in clean/sterile storerooms,[2] and millions of dollars in unaccounted for supplies and equipment.

The inspection continued and this final report details the overall findings and related recommendations. In summary, the OIG found that the Medical Center has for many years suffered a series of systemic and programmatic failures that made it challenging for healthcare providers to consistently deliver timely and quality patient care. These breakdowns also heightened the potential for fraud, waste, and abuse of government resources.

Hospitals by their very nature carry an intrinsic risk to patients as personnel contend with unpredictable situations, infection control, large numbers of vulnerable individuals with significant care needs, and changing demands on a daily basis. Given these challenges, it is critically important for hospitals to have effective core services that promote quality patient care and safety. Moreover, strong management and fiscal controls must be in place for appropriate stewardship of taxpayer-funded resources. The OIG found widespread and formidable inadequacies in many essential functions at the Medical Center that contributed to the deficiencies described in this report, including

- The inability to consistently provide supplies, equipment, and instruments to patient care areas when needed;
- Ineffective sterile processing contributing to delays or postponements of procedures due to unavailable usable instruments;

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[1] VA OIG, *Interim Summary Report: Healthcare Inspection—Patient Safety Concerns at the Washington DC VA Medical Center, Washington, DC*, Report No.17-02644-202, April 12, 2017.

[2] VHA Directive 1761, *Supply Chain Inventory Management*, 2016, p. 3, uses the term "clean/sterile storeroom" to mean a primary or secondary inventory point location where clinical items are stored to protect them from accidental contamination. VHA Directive 1116 (2), *Sterile Processing Services*, 2016, p. 4, uses the term Sterile Storage Area to mean an area designed to store clean/sterile supplies or instruments and to protect them from contamination. Within the context of this report, the OIG uses the term clean/sterile storerooms to describe primary and secondary storage areas containing medical supplies, instruments, or equipment that are sterile or otherwise clean and ready for use on patients.

- The lack of consistently clean storage areas for medical supplies and equipment;
- The failure to accurately and consistently track and trend patient safety events;
- Excessive vacancies in leadership positions and other pervasive staffing issues across multiple departments, including Logistics, Prosthetics, Sterile Processing, and Environmental Management Services;
- More than 10,000 open and pending prosthetic and sensory aid consults as of March 31, 2017, causing some patients to wait months for needed items;
- Financial and inventory systems producing inadequate data, lacking effective internal controls, and yielding no assurances that funds were appropriately expended;
- Approximately $92 million in supplies and equipment being charged to purchase cards over a two-year period without proper controls to ensure the purchases were necessary and cost-effective;
- Underutilization of the prime vendor contract that was designed to purchase supplies at more favorable prices;
- More than 500,000 noninventoried items maintained in an inadequately secured warehouse; and
- Patient protected health information (PHI) and personally identifiable information (PII) stored in unsecured areas.

Despite these significant issues, the OIG did not find evidence of patient deaths or other adverse clinical outcomes resulting from these deficiencies. This was due in large part to the efforts of a number of committed healthcare professionals who worked around these challenges and improvised as necessary to provide veterans with the best possible services under the circumstances. For example, in a number of situations, doctors and other health professionals borrowed supplies from a nearby hospital, conducted their own inventories, and took other steps in efforts to provide patients with quality and timely care. However, these stopgap measures are not accordant with an effectively managed healthcare facility. Moreover, patients were put at risk, such as when the lack of supplies or instruments caused surgical procedures to be canceled or delayed.

The dysfunctions identified at the Medical Center were prevalent and deeply intertwined. They could not be attributed to any single individual, but rather were the result of inadequate actions and accountability across many services and positions. The OIG encountered a culture of complacency among VA and Veterans Health Administration (VHA) leaders at multiple levels who failed to address previously identified serious issues with a sense of urgency or purpose. In interviews, leaders frequently abrogated individual responsibility and deflected blame to others.

Since 2013, there were reports and documentation of many of these problems that leaders at the Medical Center and its oversight entities, including the Veterans Integrated Service Network (VISN) 5 and the VHA, failed to adequately address (see Appendix B, Relevant Reports). Despite the many warnings and ongoing indicators of serious problems, leaders failed to engage in meaningful interventions or effective remediation.

This report is organized into the following four broad areas:

1. ***Risk of Harm***: Whether patients were placed at risk for experiencing adverse clinical outcomes because of the Medical Center's inability to ensure that supplies and instruments reached clinical areas when and where they were needed.[3]
2. ***Service Deficiencies Affecting Patient Care***: Whether deficiencies in the Medical Center's services that manage inventory, prepare medical instruments for use, procure prosthetic devices, and hire qualified personnel affected healthcare providers' ability to provide quality and timely services.
3. ***Lack of Controls Over Assets***: Whether Medical Center practices put medical equipment and other assets of the federal government at risk for fraud, waste, and abuse.
4. ***Failures in Leadership****:* Whether leaders at the Medical Center, VISN 5, and Veterans Health Administration Central Office (VHACO) effectively addressed Medical Center problems and unsafe conditions.

A summary of key findings within each of these four areas follows:

1. Risk of Harm

Although the OIG did not identify patients who suffered death or other adverse clinical outcomes as a result of the identified problems, veterans were put at risk because important supplies and instruments were not consistently available in patient care areas. The OIG identified cases in which

[3] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in diagnosis, a change in the course of treatment, or a significant change in the patient's level of care. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays and cancellations associated with the deficiencies discussed in this report may impact the convenience and quality of care received by veterans, some of whom travel long distances to seek care from a VA hospital. The OIG was unable to quantify the frustration, confusion, or disturbances in a veteran's activities of daily living that may have resulted from these deficiencies and focused its evaluation of patient harm in terms of adverse clinical outcomes.

- Needless hospitalizations (with attendant risks) occurred when patients' procedures were canceled following their admission, sometimes for overnight stays, because items could not be accessed in time for scheduled surgeries;
- Patients received unnecessary anesthesia when scheduled procedures were delayed to track down or borrow items (prolonging anesthesia) or rescheduled (requiring a second round of anesthesia);[4] and
- Surgeons sometimes relied on instruments that were available rather than those they were most comfortable in using, which resulted in not being able to use preferred techniques.

In addition, the OIG found

- More than 300 patient safety events involved a reported problem with supplies, instruments, or equipment from January 1, 2014, through September 6, 2016, with more than 100 of these events not reported to the VHA National Center for Patient Safety as required by VHA policy;[5] and
- The Patient Safety Manager failed to accurately and effectively track and trend patient safety events, resulting in the Medical Center missing opportunities to conduct Aggregated Reviews of supply, instrument, or equipment issues to identify and correct problems.

2. Service Deficiencies Affecting Patient Care

The extensive deficiencies identified by the OIG that impeded healthcare providers' efforts to deliver quality patient care included the following:

- The lack of an accurate inventory resulted in staff not knowing with any certainty which items they had or the available quantities.
- Clinical staff routinely had difficulty finding supplies and equipment that healthcare providers needed because there was no reliable method for locating items in storage areas.
- In August 2017, the VISN Chief Logistics Officer stated that of a total of 6,694 items maintained in all the primary storage areas that should have been entered in

[4] General anesthesia can result in serious complications, such as heart attacks or stroke, allergic reactions, or even death. In addition, patients often experience a variety of uncomfortable minor side effects, such as nausea.
[5] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

the VHA-authorized inventory system—the Generic Inventory Package (GIP)—783 of them were entered into and managed by GIP.

- Limited OIG physical inspections indicated that items entered into GIP did not consistently match what was actually on the shelves in warehouses, leaving personnel to constantly search for the items.
- The same items were ordered multiple times because healthcare providers lacked confidence that supplies would be available when needed for patient procedures.
- Because the Medical Center had not entered data into the inventory system as required, the auto-generate function for placing orders when supplies were low could not be used, which may have contributed to shortages of supplies in patient care areas.
- As of June 27, 2017, half of the clean/sterile storerooms that the OIG inspected did not meet selected infection prevention criteria and nearly one-third did not meet selected cleanliness criteria. Those conditions were largely addressed by September 2017 with the contracting of additional personnel.
- Problems in the sterile processing of instruments included
    - Discolored or broken instruments reaching clinical areas,
    - Incomplete documentation of competencies for the technicians responsible for sterilizing instruments and equipment,
    - An ineffective Sterile Processing Service quality assurance program to ensure that instruments were cleaned appropriately prior to being returned to a clinical area, and
    - No reliable way for ensuring that instrument sets sent back to clinical areas were complete and ready for use.
- As of March 31, 2017, more than 10,000 consults (requests by clinical staff to order items for patients) for prosthetic items ranging from eyeglasses and hearing aids to surgical implants and artificial limbs were open or pending.
- Services and departments responsible for supply, instrument, and equipment procurement, storage, and delivery to clinical areas were understaffed and had hiring problems that went unaddressed by Human Resources Management.

3. Lack of Controls Over Assets

The Medical Center continually mismanaged significant government resources and protected information. Its financial and inventory systems produced inadequate data, lacked effective

management controls, and yielded no reasonable assurance that funds were appropriately expended. As a result, the OIG cannot estimate the loss to VA as a result of these failings.

A number of deficiencies put government resources at risk for fraud, waste, and abuse:

- There was excessive use of government purchase cards for medical equipment and supply purchases (89 percent of the Medical Center's total purchase card use was for medical supplies) instead of approved federal contracts that leverage buying power and help ensure appropriate pricing and purchasing.
- A general lack of controls was found over acquisition of medical supplies and equipment, including the inability to consistently provide documentation such as purchase orders, invoices, receiving reports, or other item-level records required for proper auditing.
- The Medical Center failed to segregate duties so that the same individual was not both purchasing and receiving or inventorying goods to ensure the integrity of procurement processes.
- The Medical Center lacked an updated and accurate inventory for nonexpendable equipment.
- There was unsecured access to and mismanagement of more than 500,000 items accumulated in an off-site warehouse, which included purchases that did not meet Medical Center needs, overstocked items, and some items that appeared damaged.
- Because of failures in Records Management, more than 1,300 boxes of unsecured documents, including patient PHI and PII were found in various locations including the off-site warehouse, on-site storage, the Medical Center basement, and a dumpster.

4. Failures in Leadership

Information and documentation outlining some of the failings in the Medical Center reached responsible officials in the Medical Center, VISN 5, and VHACO as early as 2013, but actions taken did not effectively remediate the conditions. The OIG noted the following:

- From 2013 to 2016, the Medical Center and VISN 5 received at least seven written reports detailing significant deficiencies in Logistics, Sterile Processing, and other Services, many of which were identified as persistent at the time of the OIG 2017 on-site visits.[6]

[6] See Appendix B: Relevant Reports.

- Many recommendations from previous reports concerning the sterile processing of instruments and Logistics Service functions were deemed implemented or "closed" but were not effectively addressed by the Medical Center.
- VISN 5 leaders and some VHACO personnel were aware of many of the problems identified in this report, and did not ensure that adequate corrective action had been taken by the Medical Center to address them.
- Methods used by the VISN and VHACO to oversee the Medical Center were either inadequate or did not include data on key aspects of Medical Center operations.

It is hoped that the findings and recommendations of this inspection will promote positive change at the Medical Center to support the care of veterans served at that facility. Since the issuance of the OIG Interim Report, the Medical Center has made progress in reducing the number of open and pending prosthetic consults, updating standard operating procedures and competencies in sterile processing of instruments, and the overall cleanliness of storage areas, among other improvements. However, the magnitude, breadth, and longevity of the problems likely means it will take some time to fully correct the conditions that exist at the Medical Center. While the findings and recommendations made in this report should improve patient safety and the timeliness and quality of services at the Medical Center, leaders of all VHA healthcare facilities could benefit from closely reviewing the findings and recommendations to help identify and address any similar problems in their facilities as well.

MICHAEL J. MISSAL
Inspector General
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Contents

Abbreviations

CFO	Chief Financial Officer
CLO	Chief Logistics Officer
ECGB	Executive Committee of the Governing Board
ED	Emergency Department
EHR	electronic health record
EIR	Electronic Incident Reporting
EMS	Environmental Management Service
ENT	Ear, Nose, Throat
GI	Gastrointestinal
GIP	Generic Inventory Package
HR	Human Resources Management
JPSR	Joint Patient Safety Reporting
MEC	Medical Executive Committee
NPOSP	National Program Office for Sterile Processing
OIG	Office of Inspector General
OR	Operating Room
PSM	Patient Safety Manager
QC	Quality Council
RCA	Root Cause Analysis
RME	reusable medical equipment
SAC	Severity Assessment Code
SOP	Standard Operating Procedure
SPS	Sterile Processing Services
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VHACO	Veterans Health Administration Central Office
VISN	Veterans Integrated Service Network

Introduction

On March 21, 2017, the Department of Veterans Affairs (VA) Office of Inspector General (OIG) received allegations from a confidential source describing serious supply and financial mismanagement at the Washington DC VA Medical Center (Medical Center). The OIG assessed the allegations and related documentation and found that both patients and government assets were at risk. As a result, the OIG took the unusual step of issuing an Interim Report in April 2017. Findings included

- Inaccurate and underutilized supply, instrument, and equipment inventories that made it difficult to meet healthcare provider and patient needs;
- Inadequate product safety recall processes;
- Dirty conditions in some clean/sterile storerooms;[7]
- Millions of dollars in noninventoried supplies and equipment; and
- Numerous vacancies in key positions that would make remediation of these conditions difficult.[8]

Before the Interim Report was issued, the Veterans Health Administration (VHA) established an incident command center and staff were detailed from other facilities to assist with getting supplies, instruments, and equipment to patient care areas. On the same day that the Interim Report was released, VHA transferred the Medical Center Director to an administrative position and named an Acting Medical Center Director to oversee immediate remedial actions.[9]

An OIG team of auditors, healthcare inspectors, criminal investigators, and other subject matter experts continued and expanded their review following the release of the Interim Report. Despite some progress by the Medical Center on its inventory and other systems (such as reducing the

[7] VHA Directive 1761, *Supply Chain Inventory Management*, 2016, p. 3, uses the term "clean/sterile storeroom" to mean a primary or secondary inventory point location where clinical items are stored to protect them from accidental contamination. VHA Directive 1116 (2), *Sterile Processing Services*, 2016, p. 4, uses the term Sterile Storage Area to mean an area designed to store clean/sterile supplies or instruments and to protect them from contamination. Within the context of this report, the OIG uses the term clean/sterile storerooms to describe primary and secondary storage areas containing medical supplies, instruments, or equipment that are sterile or otherwise clean and ready for use on patients.

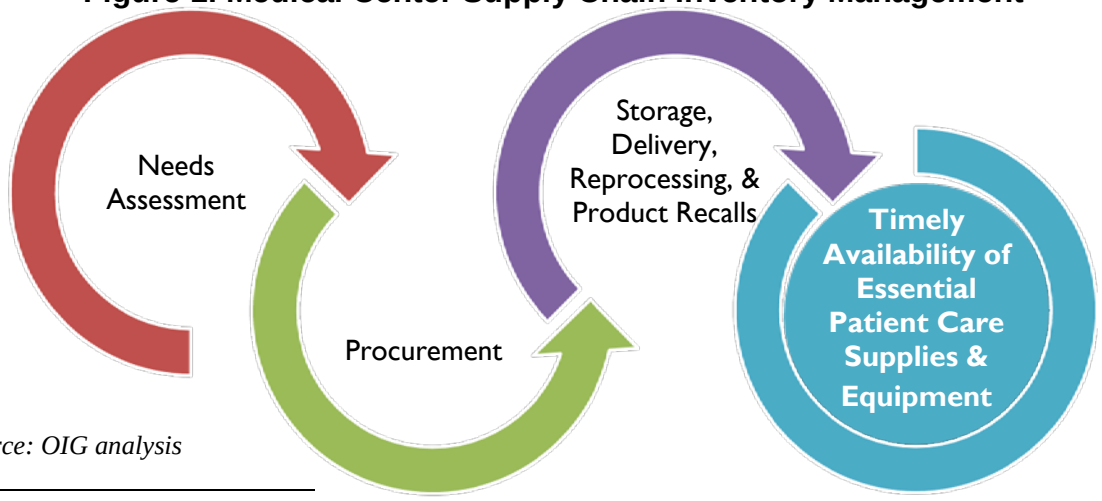
[8] VA OIG, I*nterim Summary Report: Healthcare Inspection—Patient Safety Concerns at the Washington DC VA Medical Center, Washington, DC*, Report No.17-02644-202, April 12, 2017.

[9] The Medical Center Director was Brian Hawkins. The OIG published *Administrative Investigation: Failure to Follow VA Policy, VA Medical Center Washington, DC*, Report No. 15-01119-315, August 1, 2017, that concluded Mr. Hawkins violated VA policy by transferring sensitive VA information to personal email accounts. VA removed Brian Hawkins from his position as the Medical Center Director and subsequently announced firing Mr. Hawkins on September 20, 2017, "for his failure to provide effective leadership to the D.C. Medical Center."

number of open and pending prosthetic consults and improving the cleanliness of clean/sterile storerooms), the review revealed persistent deficiencies in the ability of the Medical Center to ensure medical supplies and instruments were available when and where they were needed for patient care. The review revealed clinical staff at the Medical Center took steps to help make certain that supplies and instruments were available so that patients received the care they needed despite these deficiencies. The OIG also uncovered additional issues that increased the potential for fraud, waste, and abuse of government resources, including excessive purchase card use and inadequate documentation of information needed for accurate budgeting and expenditures.

Many of the identified problems were related to how supplies and inventory were managed. Traditionally, effective supply and inventory processes have been viewed as only important for sound financial management of hospitals, and not necessarily as an essential part of securing patient safety.[10] In fact, they are essential to both. In the VA system, multiple hospital components must engage with clinical staff to (1) determine what supplies, instruments, and equipment healthcare providers and their patients need for quality and timely patient care; (2) coordinate closely to make certain that the proper instruments, supplies, and equipment are procured; and (3) properly track, store, and ready items for use when needed in clinical areas.[11] These VA hospital components include Logistics, Sterile Processing, Prosthetics, Environmental Management, and Fiscal Services; Patient Safety Programs; and Human Resources (HR) Management.[12] (See Background for more information on related services in VHA facilities.)

Figure 1. Medical Center Supply Chain Inventory Management



Source: OIG analysis

[10] The Mitre Corporation. *Independent Assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs*, September 1, 2015. This report identified priority areas for reform within VA, including supply chain management, and noted a number of implementation barriers within VHA.

[11] Commission on Care. *Final Report of the Commission on Care*, June 30, 2016, accessed September 15, 2016, https://s3.amazonaws.com/sitesusa/wp-content/uploads/sites/912/2016/07/Commission-on-Care_Final-Report_063016_FOR-WEB.pdf. The report included recommendations for VHA improvements to supply chain management systems.

[12] The OIG uses the term "services" to include the various hospital components/departments discussed in this report.

If even one of these services fails to function appropriately, it can affect the efficiency of a wide range of clinical services. When multiple services fail to function as intended, patients can experience delays in getting needed quality care. Fraud, waste, and abuse in the purchasing and management of medical supplies and equipment also can occur unchecked. This places patients and assets of the federal government at risk. Such was the case at the Medical Center according to the OIG Interim Report findings.

To more fully understand why failures in these services occurred at the Medical Center, and what the impact of those failures were, OIG continued and expanded its review to address the following questions.

1. ***Risk of Harm***: Whether patients were placed at risk for experiencing adverse clinical outcomes because of the Medical Center's inability to ensure that supplies and instruments reached clinical areas when and where they were needed[13]
2. ***Service Deficiencies Affecting Patient Care***: Whether deficiencies in inventory management, preparing medical instruments for use, procuring prosthetic devices, and hiring qualified personnel affected healthcare providers' ability to deliver quality and timely services
3. ***Lack of Controls Over Assets***: Whether the Medical Center's practices put medical equipment and other assets of the federal government at risk for fraud, waste, or abuse
4. ***Failures in Leadership***: Whether leaders at the Medical Center, Veterans Integrated Service Network (VISN) 5, and Veterans Health Administration Central Office (VHACO) effectively addressed Medical Center problems and unsafe conditions

Medical Center Profile

The Medical Center, located within VISN 5, consists of a hospital and four Community Based Outpatient Clinics. VA classifies the Medical Center hospital as Level 1a,[14] a type of hospital that provides both general and specialty surgical services. The Medical Center served 72,265

[13] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in diagnosis, a change in the course of treatment, or a significant change in the patient's level of care. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays and cancellations associated with the deficiencies discussed in this report may impact the convenience and quality of care received by veterans, some of whom travel long distances to seek care from a VA hospital. The OIG was unable to quantify the frustration, confusion, or disturbances in a veteran's activities of daily living that may have resulted from these deficiencies and focused its evaluation of patient harm in terms of adverse clinical outcomes.

[14] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

patients in fiscal year (FY) 2016 and performed more than 3,000 surgical procedures from April 2016 through March 2017. The District of Columbia Department of Health lists 14 privately-owned hospitals in the Washington, DC, metropolitan area. The Medical Center is located within walking distance of several of these hospitals.

Background

This section outlines the critical importance of leadership in specific services, particularly those within the Medical Center that ensure supplies, instruments, and equipment reach healthcare providers and patients who need them.[15] It examines the roles and responsibilities of Logistics Service, Sterile Processing Services (SPS), Prosthetics Service, Environmental Management Service (EMS), Fiscal Service, Patient Safety Programs, and HR relevant to the problems identified within this report. It provides some insights into who was positioned to identify the problems that have persisted at the Medical Center and who can make certain adequate changes are made going forward.

One cannot overstate the need for all of these services to work effectively—alone and in coordination—to enable proper purchasing and asset management as well as quality patient care. For supply, instrument, and equipment management, while costs are an issue,

> *[t]he ultimate goal of the supply chain is to deliver materials and information in order for patients to receive quality care. An effective supply chain brings in the right materials and information at the right time, with the right quantities, to the right place. This can have a direct, positive impact on patient care by reducing risk and errors, eliminating operating room waits and cancellations, and reducing the length-of-stay.*[16]

VA has initiated a modernization plan to improve supply chain inventory management.[17] However, in order to effectively carry out the plan, multiple VA and VHA services must coordinate the selection and procurement of appropriate inventory and then properly maintain, store, and deliver the supplies, instruments, and equipment so they are ready to use when and where they are needed. These efforts need to be supported by an adequate number of qualified staff with clear roles and responsibilities. The problems cataloged in this report also reach beyond the availability of needed supplies, equipment, and instruments. The lack of fiscal and management controls could potentially affect nearly all Medical Center operations.

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[15] VHA Directive 1761(1), *Supply Chain Inventory Management*, October 24, 2016. "[Supply Chain Management] is the integration and alignment of people, processes, and systems across the supply chain to manage all product/service planning, sourcing, purchasing, delivering, receiving, and disposal activities."

[16] Dean Elmuti et al. "Challenges and Opportunities of Health Care Supply Chain Management in the United States," *Health Marketing Quarterly* 30, no. 2, (2013): 128–143.

[17] VHA Directive 1761(1).The directive was issued after VA received a recommendation to develop a plan to replace the Prosthetics Inventory Package and Generic Inventory Package with a comprehensive modern inventory management system.

Table 1. Common Inventory and Supply Terms

Term	Definition
Expendable Supplies	Disposable commodity items typically used once[18]
Nonexpendable Equipment	Equipment that has a continuing use, is not consumed in use, is of a durable nature with an expected service life of two or more years, has an acquisition cost of $300 or more, and does not become a fixture or lose its identity as a component of other equipment or plant[19]
Surgical Instruments in Use	Instruments prepared by SPS for the Operating Room[20]
Prosthetics and Implants	Device(s) that support or replace the loss of a body part or function[21]

Source: OIG analysis

Responsibilities for Ensuring Supplies Are Ready for Use When Needed Involve Many Individuals and Services

The Secretary of the VA directs the second largest federal department. VA is composed of the Veterans Health Administration (VHA), Veterans Benefits Administration, and Veterans Cemetery Administration. This report focuses on VA oversight of only the VHA, particularly its supply chain inventory management functions and how these impacted operations at the Medical Center.

The Under Secretary for Health (USH) is responsible for the overall leadership and direction of VHA,[22] which consists of 140 medical centers and more than 1,200 outpatient facilities.[23] The medical centers are grouped into "integrated networks" known as Veterans Service Integrated Networks (VISNs). Each is led by a VISN Director tasked with "budgeting and planning veterans' health care for a particular geographic area."[24] The Medical Center is part of VISN 5.[25]

[18] VHA Directive 1761(1), p. 4.

[19] VHA Handbook 7002-1, *Logistics Management Procedures*, April 14, 2011.

[20] For purposes of this report, the OIG distinguishes surgical instruments in use from those in stock because of differences in responsibilities for who inventories and distributes those items. For example, a surgical instrument in use would be a reusable medical equipment item inventoried and stored by SPS, while a stock surgical instrument would remain in the Generic Inventory Package (the Medical Center's supply inventory system managed by the Logistics Service) until distributed to SPS.

[21] VHA Handbook 1173.1 *Eligibility*. November 2, 2000. This handbook was scheduled for recertification on or before the last working day of July 2005 but has not yet been recertified.

[22] VA 2017 Functional Organization Manual - v4.0, *Description of Organization Structure, Missions, Functions, Activities, and Authorities*, p. 134, Figure 12.

[23] "Department of Veterans Affairs Statistics at a Glance," National Center of Veterans Analysis and Statistics, accessed October 4, 2017, https://www.va.gov/vetdata/docs/Quickfacts/Stats_at_a_glance_06_04_16.PDF.

[24] Adam Oliver, "The Veterans Health Administration: An American Success Story?" *Milbank Quarterly* 85, no. 1, (2007): 5–35, accessed October 4, 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/pdf/milq0085-0005.pdf.

The USH issues directives that establish mandatory VHA policies and handbooks that prescribe procedures and/or operational requirements. Directives and handbooks outline the duties and responsibilities of VHA, VISN, and medical center offices, services, and staff on specific matters. The Deputy Under Secretary for Health for Operations and Management, who oversees the VISN Directors, may issue memoranda that outline specific standard operating procedures (SOPs) or policy clarifications.

The issue of greatest focus in this report is the failure of the Medical Center to ensure that providers and patients had the right supplies, instruments, and equipment when and where they were needed in accordance with VHA, VISN, and Medical Center policies, and commonly accepted practices for effective hospital management. For this process to be successful, the multiple systems involved in identifying, acquiring, storing, and transporting items to clinical areas must be organized, coordinated, and highly reliable. The responsibilities of individuals who are in positions of leadership at different levels in VA and VHA overseeing the essential services are detailed below.

Logistics Service

Logistics Service staff at VHA, VISN, and medical center levels are tasked with implementing and maintaining an inventory of expendable supplies using the Generic Inventory Package (GIP) software, and training staff to effectively use the system.[26] The VHA Procurement and Logistics Office is responsible for the VHA supply chain inventory management program including the following tasks:

- Collecting and managing data
- Performing quality assurance
- Implementing tools for corrective action[27]

VISN leaders oversee their medical centers' performance standards, and medical center leaders ensure proper resources such as space, staffing, and technology are allocated to meet supply management needs.[28] Logistics Service officers at the VISN and medical center levels collaborate with contracting officers, assist with recall procedures, and oversee inventory accounts including an annual physical inventory count of equipment.[29]

[25] "VA Capitol Health Care Network," U.S. Department of Veterans Affairs, accessed September 15, 2017, https://www.va.gov/visn5.
[26] VHA Directive 1761(1).
[27].VHA Directive 1761(1).
[28] VHA Directive 1761(1).
[29] VHA Directive 1761(1).

SPS

The VHA National Program Office for Sterile Processing (NPOSP)[30] Director develops policies for the standardization and reprocessing of reusable medical equipment (RME),[31] temperature and humidity requirements for storage, and workplace controls for personnel who perform reprocessing. Within individual medical facilities, the director is responsible for ensuring compliance with SPS policies and procedures related to the sterilization of instruments and equipment.[32] In general, SPS has the primary responsibility in facilities to decontaminate, disinfect, and/or sterilize specified RME and instruments. SPS supports the medical facility by maintaining a continuous flow of processed instruments to all points of use. Further, a "quality assurance program must be in place to ensure appropriate and safe reprocessing is being performed."[33]

Prosthetics Service

While Logistics Service staff manage both expendable and nonexpendable supplies and equipment, Prosthetics Service personnel manage prosthetic and sensory aid devices prescribed for individual patients. Prosthetics Service personnel also collaborate[34] with the Logistics Service to consolidate processes where possible and eliminate redundancies in contract requirements.[35] Per VHA policy, quality patient care must be provided by furnishing properly prescribed prosthetic equipment, sensory aids, and devices, in the most economical and timely manner for veterans in need of such devices.[36]

[30] VA 2017 Functional Organization Manual - v4.0, p. 205. NPOSP is organizationally aligned under the Assistant Deputy Under Secretary for Health for Clinical Operations (mail code 10NC6).

[31] VHA Directive 1116(2). RME is "equipment intended for repeated use on different patients with appropriate decontamination and other processing between uses." Reprocessing is "all of the steps performed to make a contaminated item reusable or single-patient use device patient-ready; steps may include cleaning, functional testing, repackaging, relabeling, disinfection, or sterilization."

[32] VHA Directive 1116(2).

[33] VHA Directive 1116(2).

[34] VA 2017 Functional Organization Manual - v4.0, pp. 166, 177. Prosthetic and Sensory Aids Services (PSAS) is organizationally aligned under the Office of the Assistant Deputy Under Secretary for Health for Patient Care Services.

[35] VHA Directive 1761(1). The medical facility Logistics program is responsible for inventory management of PSAS clinical items.

[36] VHA Directive 1173, *Prosthetic and Sensory Aids Services*, June 27, 2008. This directive was scheduled for recertification on or before the last working day of May 2013 and has not been recertified.

Environmental Management Service

The Medical Center Director is responsible for maintaining a "safe, sanitary and healing environment."[37] The Medical Center Chief of EMS ensures a state of physical and biological cleanliness and safe conditions for patients, visitors, and employees through proper handling of waste materials, soiled textiles, and equipment.

Fiscal Service[38]

The VA Assistant Secretary for Management/Chief Financial Officer (CFO) has responsibility for identifying, reviewing, and accounting for inventory, supplies, materials, stockpiles, and related property and for ensuring that each transaction is accompanied with sufficient supporting and auditable documentation. Physical controls and accountability reduce the risk of

- Undetected theft and loss,
- Unexpected shortages of critical items, and
- Unnecessary purchases of items already on hand.

The VISN and Medical Center CFOs have responsibilities for facility budgets and accounting requirements, including the following:

- The VISN CFO must use the VA-mandated system to meet the federal government Managerial Cost Accounting requirements. The VISN is required to use this information to support budget formulation, allocation, and execution.
- The Medical Center CFO works with the Chief Logistics Officer (CLO) to address budgetary requirements, establish fund control parameters, and complete a year-end certification letter for inventory values.[39]

Patient Safety

The National Center for Patient Safety (NCPS) is part of the VHA Office of Quality, Safety and Value and works to prevent inadvertent harm to patients consequent to their medical care.[40] NCPS develops and publishes Patient Safety Alerts (and Advisories) that concern specific issues relating to equipment, medications, and procedures that might cause harm to patients. Alerts

[37] VHA Directive 1850, *Environmental Programs Service*, March 31, 2017.

[38] VA 2017 Functional Organization Manual - v4.0, p. 290, Figure 18. VA and VHA use various terms to refer to financial management and oversight. For this report, we use the term Fiscal Service to refer to all financial offices.

[39] VHA Directive 1761(1).

[40] VHA Handbook 1050.01, *National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was scheduled for recertification on or before the last working date of March 2016 but has not yet been recertified.

communicate urgent notices that require immediate and specific action(s) by particular parties by a set deadline. In the context of supply chain inventory management, the medical center patient safety managers are responsible for documenting completion of patient safety alert actions and patient safety advisory recommendations on the VHA alerts and recalls website, to include actions related to product recalls.[41] Patient safety managers have primary responsibility for scoring the severity of reported adverse events or close calls to determine follow-up actions as needed.[42] Patient safety managers are also responsible for analyzing and reporting relevant data to NCPS.

Human Resources Management

Ultimate responsibility for effective HR management in VA is retained by the Secretary.[43] Most HR functions, however, are performed at the medical center level. Consistent with this concept, medical center leaders have the authority and the responsibility for overseeing the program in their respective facilities.[44]

[41] VHA Handbook 1050.01.
[42] VHA Directive 1068; VHA Handbook 1050.01.
[43] VA Handbook 5001 Part II, *Human Resources Management Goals, Roles, and Authorities*, pp. II–4, April 2002.
[44] VA Handbook 5001 Part II, p. II–5.

Results (Part I): Risk of Harm

The Institute of Medicine defines patient safety as "the prevention of harm to patients." It emphasizes the avoidance of harm, as well as the need for rigorous responses to any identified adverse conditions or events. Patient safety requires that healthcare facilities take necessary action before patients suffer adverse clinical outcomes. The OIG's April 2017 Interim Report identified systemic breakdowns at the Medical Center that placed patients at risk for adverse clinical outcomes and recommended immediate steps be taken to mitigate that risk.

This section provides examples of how patients were at risk because of ongoing problems with ensuring the availability of supplies, instruments, and equipment in patient care areas when needed. It further describes weaknesses in the VHA and Medical Center patient safety programs, which may have delayed leaders' understanding of the scope and severity of the problems. Although the OIG did not identify adverse clinical outcomes resulting from supply, instrument, or equipment issues, the OIG concluded that the absence of adverse outcomes resulted, in large part, from the actions taken by physicians, nurses, and other personnel who made certain that patients received the care they needed despite these challenges.

The OIG's additional findings in this report are drawn from

- Interviews with healthcare providers,
- Reviews of individual patient cases, and
- Examinations of systems-level structures and control measures.

Although the Medical Center has taken some corrective actions and personnel have reported areas of improvement after the Interim Report's release, the Medical Center continued to experience problems in ensuring that supplies, instruments, and equipment reached clinical areas when and where they were needed for patient care.

Interviewees Reported that Missing Supplies, Instruments, and Equipment Affected Patient Care

Of 30 healthcare providers interviewed, at least 24 reported having had problems with supplies, instruments, or equipment. Multiple providers reported that they "made do" with available equipment and supplies because the instruments that surgeons were most comfortable using were not readily available. Interviews also revealed the following:

- Twelve healthcare providers reported that procedures were canceled or delayed due to supply, instrument, or equipment issues.[45]
- Eleven healthcare providers said that at some point during a patient's care, staff had to leave the Medical Center and go to a hospital "across the street" to obtain needed supplies.[46]
- Thirteen of the healthcare providers stated that they had reported their concerns to the Chief of Surgery.
- Twelve healthcare providers stated that they had reported supply, instrument, or equipment concerns to the Medical Center Chief of Staff.
- At least four healthcare providers reported some improvement in their ability to obtain needed supplies, instruments, or equipment after publication of the OIG's Interim Report.

OIG Patient Case Reviews Found Risk of Adverse Clinical Outcomes

The Interim Report provided a range of examples in which patients were put at risk because of the lack of immediate access to supplies. These included the unavailability of supplies for testing laparoscopes; bloodlines for dialysis patients; oxygen nasal tubing, and other significant items. The items had to be borrowed or resulted in procedures being rescheduled, or conducted without supplies on hand that might be needed. In this section of the report, the OIG addresses not only patient risk associated with the lack of expendable supplies, but also risk related to the unavailability of surgical instruments.

The OIG independently reviewed the care provided to 124 Medical Center patients to determine if they experienced adverse clinical outcomes because their healthcare provider did not have the appropriate supplies, instruments, or equipment (as outlined in Table 2).

Table 2. OIG Patient Case Review Methodology for Assessing Adverse Clinical Outcomes

Source	Methodology
Staff Referrals	The OIG obtained a list compiled by a staff member at the Medical Center of 19 patients who experienced operating room delays or cancellations between April 5, 2016, and March 24, 2017, that allegedly had an adverse impact on their care. An OIG physician reviewed all 19 patients' electronic health records to determine if an adverse clinical outcome occurred.

[45] Clinicians were generally unable to recall the specific names of patients involved in the cancellations, resulting in the OIG not being able to further assess the impact of these reported cancellations on patients.

[46] The Washington Hospital Center, a private facility, is located across the street from the Medical Center.

Table 2 (*continued*)

Source	Methodology
Incident Reports	The OIG obtained 868 incident reports completed between January 1, 2014, and March 30, 2017. An OIG team of registered nurses reviewed the reports and identified those concerning patient safety that involved supplies, instruments, or equipment. Their analysis yielded a total of 56 unique patients for further review. An OIG physician reviewed all 56 patients' electronic health records to determine if an adverse clinical outcome occurred.
Canceled Surgical Procedures	The OIG reviewed all canceled surgical procedures occurring between 2015 and 2017 in which the Medical Center recorded unavailable instruments or equipment as the reason for the cancellation, or failed to record a reason for the cancellation. There were 39 cases identified in which the cancellation potentially resulted from unavailable instruments or equipment. An OIG physician reviewed each case to determine if an adverse clinical outcome occurred.
Interviews	The OIG identified an additional 10 cases for review from interviews or referrals from Medical Center staff. An OIG physician reviewed each case to determine if an adverse clinical outcome occurred.

Source: OIG analysis of patient electronic health records

Of the 124 patient cases reviewed, problems were documented with supplies, instruments, or equipment that affected 74 patients from January 1, 2014, through September 2017. The remaining 50 patients' records and other documentation did not contain evidence of such difficulties. While the OIG did not find that patients suffered adverse clinical outcomes, the OIG found several examples that illustrated an impact on patients when supplies, instruments, and equipment were not available when needed.

As a final check on the availability of instruments, the surgical team conducts a time-out generally prior to the patient undergoing anesthesia to confirm the patient's identity and procedure. During the time-out, the team must review a procedure checklist and concur verbally to each item. The checklist must include whether specialty equipment needed for an operative procedure is available.[47] At the Medical Center, surgeons and operating room (OR) staff maintained a list of instruments that needed to be available for particular procedures, including ones specified by the operating surgeon, and updated the list electronically.

Unnecessary Anesthesia and Alternative Surgical Techniques Due to Failure to Ensure Availability of Instruments

The following three examples describe patients who received anesthesia unnecessarily or providers who had to use alternative techniques due to the unavailability of instruments or supplies at the time of a planned surgical procedure. One of the three incidents occurred after the OIG issued its Interim Report.

[47] VHA Directive 1039, *Ensuring Correct Surgery and Invasive Procedures*, July 26, 2013.

Patient A. *In 2017, Patient A was admitted for a planned surgical procedure. After the patient received general anesthesia, the surgeon determined that an instrument that she needed to perform the surgery (a Henley retractor) was not present in the OR suite and canceled the procedure. The device was not on a previously developed list that identified the instruments the surgeon felt most comfortable using for particular procedures and there was only one available for the surgeon's use in the Medical Center. It had not been sterilized in the week since its last use. While the patient underwent the procedure two days after the cancellation without complications, receiving a general anesthetic unnecessarily placed the patient at risk.*[48]

Patient B. *In 2016, Patient B underwent a surgical procedure to remove a right lower extremity skin cancer. This procedure involved placing a piece of healthy skin over the area that had been removed. A device called a mesher is used during this process to place small holes for drainage through the skin. During the procedure, the surgeon discovered the handle to this device was missing. The surgeon made these tiny holes manually, which can result in uneven drainage from the surgical site. The patient did well postoperatively, but the skin graft did not adhere properly. Although the surgeon could not attribute this outcome to the lack of the mesher device, she told OIG inspectors that the manual technique used was not state of the art for this procedure.*

Patient C. *In 2015, Patient C was admitted for a right hip replacement and received a local anesthetic (right femoral nerve block). The appropriate surgical instruments were not available, so the patient's surgeon canceled the procedure. The patient, who could not walk immediately after the procedure, had to be admitted overnight until the effects from the anesthetic resolved — subjecting Patient C to the risks of an unnecessary nerve block and hospitalization.*[49] *The patient was readmitted three days later for a successful hip replacement and did not experience an adverse clinical outcome.*

Unnecessary Hospitalization or Prolonged Surgical Procedure Due to the Lack of Expendable Supplies

In addition to unavailable surgical instruments, providers at times did not have expendable supplies they needed in the OR.[50] The Interim Report identified a number of instances in which those supplies were not available, including the following:

[48] General anesthesia can result in serious complications, such as heart attacks or stroke, allergic reactions, or even death. In addition, patients often experience a variety of uncomfortable minor side effects, such as nausea.

[49] "Problems due to Hospitalization," Merck Manual, accessed November 30, 2017, https://www.merckmanuals.com/home/special-subjects/hospital-care/problems-due-to-hospitalization. These risks include infection at the site of the nerve block injection, persistent pain or discomfort, and the intrinsic risks of hospitalization such as increased risk of falls, delirium (mental status changes associated with alterations in medications, environment or other factors) and other types of hospital-acquired infections.

[50] For purposes of this review, implants are included as an expendable supply because they are tracked in GIP, and therefore affected by the lack of reliable inventory systems.

- *In spring 2017, the OIG received an email stating that the OR ran out of sequential compression devices (SCDs). These are devices placed on patients' legs to prevent blood clots during surgery. Surgeries proceeded without the devices. The Deputy Chief Logistics Officer confirmed that the Medical Center was out of at least some sizes of SCDs during the month of July. The reorder point level (the level at which the Medical Center should reorder a supply because it is getting low) had not been established correctly in GIP.*[51]
- *In spring 2016, four prostate biopsy surgical procedures were canceled because prostate biopsy guns were out of stock. A staff member wrote an email to the Medical Center Director, recommending an OR "stand down" until the inventory situation in the OR could be remedied. The Medical Center Director could not recall receiving this email, or taking any action relative to this incident.*

The OIG's subsequent review of additional patient cases involving the lack of available supplies in the operating room revealed other examples, as described below. One of the patient cases occurred after issuance of the Interim Report.

Patient D. *In 2017, Patient D was admitted in preparation for a procedure the following day to treat liver cancer, but the procedure was canceled. According to an email from the interventional radiologist who later performed the procedure, the postponement was the result of the Medical Center lacking a necessary supply item (embolic beads). The patient was readmitted 13 days later, received the necessary procedure, and was discharged after a night spent at the Medical Center. Although the patient did not experience an adverse clinical outcome as a result of the procedural delay, the unnecessary additional hospitalization carried intrinsic risks.*[52]

Patient E. *In 2016, Patient E had surgery to repair an inguinal hernia (a condition in which tissue pushes through abdominal muscles).*[53] *The surgeon intended to use a specific type of mesh. After the operation began, the surgeon realized that the type of mesh he intended to use during the procedure was not available at the Medical Center. While the operation was ongoing, a member of the surgical staff acquired the mesh from a medical facility "across the street." After the mesh was placed, the surgery proceeded uneventfully and the patient was discharged without complication. The surgeon estimated that additional anesthesia time for this patient was minimal*

[51] The Medical Center has established new stock levels in GIP for this item; as of September 20, 2017, there were 250 SCDs stocked.

[52] As noted, these risks include infection at the site of the nerve block injection, persistent pain or discomfort, and the intrinsic risks of hospitalization such as increased risk of falls, delirium (mental status changes associated with alterations in medications, environment or other factors) and other types of hospital-acquired infections.

[53] "Patient Care & Health Information > Diseases & Conditions > Inguinal hernia," Mayo Clinic, accessed November 30, 2017, https://www.mayoclinic.org/diseases-conditions/inguinal-hernia/symptoms-causes/syc-20351547.

and unlikely to have been clinically significant. The OIG was unable to confirm the amount of extra anesthesia time attributable to the lack of the mesh availability. However, failing to obtain foreseeably needed surgical supplies in advance elevated patient risk.[54]

VHA does not specifically require that healthcare providers document supply, instrument, or equipment issues in the patient's electronic health record (EHR). Consequently, the OIG was limited in being able to determine the total number of patients who may have been affected. Patient cases highlighted in this review were identified primarily through providers or patient safety reports. Because some of these patient cases happened more than a year ago, staff often could not recall details beyond those recorded in the reports or EHRs.

How Healthcare Providers Mitigated Patient Risk

Healthcare providers were able to clearly relate how they worked to reduce the risk to patients that resulted from Medical Center supply and inventory problems. In addition to healthcare providers going to a nearby private hospital to borrow supplies or instruments, they often improvised by using similar instruments or conducted their own inventory to ensure patients obtained the care they needed. For example, during interviews, OIG learned the following:

- A vascular surgeon personally inventoried supplies to guarantee she had what was needed for scheduled procedures.
- A plastic surgeon repeatedly contacted vendors and Medical Center leaders to ensure implants would be available when needed.
- Healthcare providers contacted OIG team members to ask for help addressing ongoing supply shortages, even after publication of the Interim Report.

In addition to these activities taking healthcare providers' time away from patient care, highly skilled surgeons, nurses, and other healthcare professionals were put in the role of performing logistics and supply functions, which is a misuse of clinical resources and contrary to policy.[55] Healthcare providers are not trained to perform these functions, and when necessity required them to do so, they devised workarounds to manually track inventory. Consistently relying on such workarounds is not a sustainable approach to inventory management and does not advance the implementation of a highly reliable system.

[54] Finlay A. McAlister et al, "Incidence of and Risk Factors for Pulmonary Complications after Nonthoracic Surgery," *American Journal of Respiratory and Critical Care Medicine* 171, no. 5, March 1, 2005. Duration of anesthesia is an independent risk factor for certain complications in hernia repair procedures.

[55] VHA Directive 1761(1) provides that the Medical Center CLO is responsible for "[p]romoting efficient utilization of supplies by ensuring that proper items and levels are set within inventory points" and that "logistics staff, rather than clinical staff manage all medical supplies."

While the actions of these healthcare providers and other dedicated personnel mitigated the risk of adverse clinical outcomes in the patient cases the OIG reviewed, they cannot be expected to routinely take the place of a fully implemented Medical Center-wide inventory system.

Recommendations 1–3

The OIG recognizes that changes take time and that both short- and long-term strategies will be required to ensure that healthcare providers have the supplies, instruments, and equipment needed to deliver quality services to their patients and minimize patient risk. All recommendations in this report related to the "Medical Center Director" and other leaders are directed to the individual in that position—whether in an acting or permanent capacity. Recommendations directed to the Under Secretary for Health (USH) will be submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

Recommendation 1. The Medical Center Director ensures that necessary supplies, instruments, and equipment are available in patient care areas at the Medical Center when and where they are needed.[56]

Recommendation 2. The Medical Center Director requires operating room staff to conduct the final validation that all supplies, instruments, and equipment needed to perform the planned procedure and to address potential complications are in the operating room and available for use.

Recommendation 3. The Medical Center Director makes certain that the OR staff have accurate lists of surgical instruments needed for particular procedures.

A Systems-Level Look at Risk Revealed Patient Safety Program Weaknesses

Patient safety programs exist at VA medical facilities to prevent inadvertent harm to patients. By reporting and tracking adverse events and "close calls," these programs allow VA medical facilities to identify and address unsafe conditions. The OIG's Interim Report cited 194 patient safety events that Medical Center staff identified as being related to supplies, instruments, or equipment from January 1, 2014, through September 6, 2016.[57]

Following release of the Interim Report, the OIG determined that its preliminary report of 194 patient safety events was an understatement, and reflected only patient safety events entered into

[56] The Interim Report included a similar recommendation directed to the USH that required immediate action to ensure that necessary supplies, instruments, and equipment were available in patient care areas at the Medical Center when and where they are needed; the OIG has directed this recommendation to the Medical Center Director to maintain the actions the USH initiated and to prevent future issues.

[57] VA OIG's Interim Report stated this number to be 194 based on information provided by the Medical Center. After further validation, the OIG determined that one incident was not related to a supply, instrument, or equipment issue and excluded it from review.

the National Center for Patient Safety (NCPS) database from January 1, 2014, through September 6, 2016. Further analysis showed that, during that time frame, at least 376 patient safety events related to supplies, instruments, or equipment were reported within the Medical Center. Of those, 206 patient safety events were entered into the Medical Center Electronic Incident Reporting (EIR) system, but were not entered into the VHA NCPS database as required.

The following section describes the Medical Center patient safety program and the circumstances under which the program failed to score the severity of patient safety events and to identify a trend in the reporting of supply, instrument, and equipment issues. It also explains how the absence of supply controls affected capabilities to conduct product recalls as required under VHA policy.

About the Medical Center Patient Safety Program

The patient safety program is aligned under the Medical Center Director. It is staffed by a Patient Safety Manager (PSM), who has been in her role for 10 years, and two patient safety specialists. Per VHA policy, "[w]hen an adverse event or close call occurs, VA personnel may use any available or locally accepted method to notify the PSM and begin the [Medical Center's] consideration of the event."[58] The Medical Center requires that the first staff member to learn of a patient safety event initiates an incident report immediately[59] in the Medical Center electronic incident reporting (EIR) system.[60] The information in the EIR system is used by the Medical Center PSM to track and trend patient safety events for the purpose of making "recommendations to the Chief of Staff and/or the Medical Center Director for those incidents that require investigation through formal methods, including conducting a Root Cause Analysis [RCA]."[61]

VHA requires PSMs to evaluate every reported patient safety event and assign a Severity Assessment Code (SAC) score using a matrix that weighs the severity of harm incurred by the patient (or reasonable "worst case" if the incident is a close call) and the anticipated probability of recurrence of the incident. SAC ratings range from 1 (lowest magnitude) to 3. The SAC rating dictates whether additional investigation or action is required relating to the patient safety event. For example, the PSM must conduct an RCA for any incident that is assigned a SAC 3.

[58] VHA Handbook, 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This Handbook was scheduled for recertification on or before the last working date of March 2016 and has not yet been updated.

[59] DC VA Medical Center Policy Memorandum No. 00-30, *Patient Incident Reporting*, July 1, 2016.

[60] In February 2017, VHA began piloting a potential replacement for EIR, called the Joint Patient Safety Reporting (JPSR) system. From September 2016 when EIR was removed from service until the start of the JPSR pilot, Medical Center staff submitted incident reports to the PSM via email or other methods.

[61] VHA Handbook 1050.01. An RCA is a focused review that seeks to understand why a patient safety event occurred, and to identify system improvements to prevent a recurrence of the same issues.

Nationally, the VHA NCPS monitors the Patient Safety Information System (PSIS) of reported patient safety events.[62] VHA policy requires reporting and documentation of patient safety adverse events or "close calls"[63] to the NCPS using a software application called WebSPOT.[64]

Within an individual medical center, the PSM can identify emerging trends that could potentially compromise patient safety through event reporting and analysis. At the national level, the VHA NCPS analyzes data reported from all medical facilities to identify emerging trends that have the potential to compromise patient safety in multiple facilities. At the Medical Center, although data were available, the PSM did not detect the widespread nature of the supply, instrument, and equipment problems until June 2016, when the Medical Center conducted an individual RCA on an incident involving the use of expired surgical supplies during a surgical procedure.

Failures to Appropriately Score, Trend, and Record Patient Safety Events

From January 1, 2014, through September 6, 2016, at least 376 patient safety events were entered into the Medical Center EIR involving problems with the availability of supplies, instruments, or equipment. This represented 14 percent of all Medical Center patient safety events reported during that time frame.[65]

The OIG reviewed the 376 reported events and found that the Medical Center failed to score EIRs, analyze trends, and enter all events into the NCPS database, leading to missed opportunities to improve supply, instrument, and equipment-related deficiencies.

Assigning SAC Scores

Of the 376 patient safety events related to supplies, instruments, or equipment, the OIG identified at least 146 that did not have a SAC score assigned. This is inconsistent with VHA policy that requires the PSM "to assign actual and potential SAC score that then defines what further actions are necessary" for all reported patient safety events.[66] For the remaining 230 patient safety events, the PSM assigned a SAC score of 1; VHA policy does not require further review (such as the commissioning of an RCA) of incidents with a SAC score of 1. Because the SAC score provides the basis for determining the severity of events and the need for action,

[62] VHA Handbook 1050.01.

[63] VHA Handbook 1050.01. "A close call is an event or situation that could have resulted in an adverse event, but did not, either by chance or through timely intervention. Such events have also been referred to as 'near miss' incidents."

[64] VHA Handbook 1050.01.

[65] Over the nearly three-year review period, the highest number of incidents was reported in 2014 with decreasing frequency in 2015 and 2016.

[66] VHA Handbook 1050.01.

failure to consistently and appropriately code the severity of patient safety events can result in missed opportunities to improve patient safety.

Analyzing Data for Trends

A grouping with 376 patient safety events entered into the EIR system and involving problems with the availability of supplies, instruments and equipment should have been identifiable to the PSM and flagged for action and/or follow-up. This grouping also did not include the patient safety events that were reported outside of the EIR system between September 2016 and February 2017. Yet, the PSM told OIG inspectors that she did not identify patterns or trends related to supplies, instruments, or equipment during her evaluation of patient safety events.

While an RCA is not required for individual low-scoring patient safety events, VHA policy encourages the use of Aggregated Reviews for a group of similar events to determine a common cause: "systems vulnerabilities, trends, or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases."[67] VHA requires medical facilities to conduct annual Aggregated Reviews for three types of events: patient falls, missing patients, and adverse drug events. A fourth type, known as a "wild card" Aggregated Review, can be completed on a category of patient safety events of the medical facility's choosing. The National Patient Safety Improvement Handbook does not define criteria for wild card reviews.[68] The PSM could have conducted a wild card Aggregated Review to investigate why the Medical Center recorded 291 reports of supply and instrument problems in 2014 had she identified the issue.

Entering Data into WebSPOT

The OIG determined that 170 of the 376 patient safety events reported through EIRs were entered into WebSPOT and 206 events associated with supplies, instruments, or equipment were not entered. Table 3 outlines the Medical Center scoring and reporting of the identified patient safety events to the NCPS.

[67] VHA Handbook 1050.01.
[68] VHA Handbook 1050.01.

Table 3. Medical Center Severity Scoring of EIRs Entered into the NCPS Database[69]
(January 1, 2014, through September 6, 2016)

Medical Center SAC Scoring	Medical Center EIR Reports	EIR Reports Entered	EIR Reports Not Entered
No Assigned Score	146	0	146
Score of 1	230	170	60
Score of 2	0	0	0
Score of 3	0	0	0
Total Number of Incidents	**376**	**170**	**206**

Source: OIG analysis of Medical Center data

The PSM could not explain why 206 events were reported through the EIR system, but not entered into WebSPOT, the required NCPS electronic reporting program. She could only speculate that patient safety assistants failed to enter the data. The patient safety assistants who were responsible for entering the date were no longer in those roles. The OIG could not discern differences in the severity of events that were entered into WebSPOT as opposed to events that were not.

OIG staff interviewed the NCPS Director to determine why the clustering of patient safety events related to the unavailability of supplies, instruments, and equipment at the Medical Center was not identified through WebSPOT. The Director stated that staff do not review all entries for trends, but focus on those patient safety events that have been coded with a high SAC score or which occur across medical centers. VHA policy requires the NCPS to monitor its database for information that might require development of a Patient Safety Alert or Patient Safety Advisory. These alerts or advisories recommend that medical centers nationwide take certain actions that mitigate a recognized patient risk. All of the Medical Center patient safety event entries associated with supplies, instruments, or equipment were assigned the lowest SAC score, and therefore would not have been reflected in national trending analyses. The NCPS is most successful in trending patient safety events when all medical centers enter required data into the national database.

The severity, magnitude, and root causes of the Medical Center supply, instrument, and equipment challenges might have been detected earlier if the Medical Center patient safety staff had evaluated all incidents on an aggregated basis.

[69] This table includes only the number of events recorded in the Medical Center's EIR system. As discussed previously, the PSM entered events from emails or other sources into WebSPOT as well, which were considered as part of the 194 patient safety events reported by the OIG in its the Interim Report.

Failure of Oversight Committees to Track Issues and Follow Corrective Action through Resolution

Other mechanisms for aggregating information to inform VISN 5 and Medical Center leaders about emerging issues within the Medical Center include the work of quality management and safety committees. The OIG conducted an extensive review of meeting minutes from the Executive Committee of the Governing Body (ECGB), which is responsible for oversight of critical quality and patient safety monitors, and its subordinate committees. The ECGB oversees the Medical Executive Committee (MEC) and Quality Council (QC) as well as other organizational patient safety and performance improvement initiatives.

VHA policy requires the ECGB to keep minutes that describe and track issues to resolution, as well as to make recommendations to leaders.[70] The OIG review of minutes from October 2015 through April 2017 revealed a pattern of reporting and oversight deficits. In addition to the ECGB meeting minutes, the OIG reviewed meeting minutes of other committees that provide oversight for patient safety and performance improvement initiatives. As the content of these minutes are protected from disclosure (38 U.S.C. § 5705), the OIG is unable to discuss the specifics of its review. Review of the Director's morning report, which is not confidential, revealed a lack of appropriate follow-up actions for surgical instrument issues.

The OIG confirmed through interviews and analyses of documents provided that action plans, if implemented, were not consistently effective at resolving issues as evidenced by ongoing deficiencies in many areas. The VISN Quality Management Officer who has responsibility for overseeing all aspects of quality management and performance improvement at VISN 5 facilities acknowledged these concerns in an interview with OIG staff, and reported that he would be "pushing for a rapid process improvement initiative."

The Medical Center Product Recall Processes

Ensuring patient safety requires that supplies received in patient care areas are ready for use and not subject to a product recall. The Interim Report found that the lack of an effective inventory management system compromised the ability of the Medical Center to know what supplies it had, and where they were located in the event of a recall. Prior to April 2017, the Medical Center Logistics Service managed medical device or product recalls. Logistics Service staff reviewed purchase orders and relied on emails to various units to notify clinical staff to locate and remove items. Clinical staff had to visually inspect storage areas or rely on their own knowledge of which supplies, instruments, or equipment were in use to implement recalls for their units. Without an accurate inventory, neither Logistics Service nor clinical staff had a way of verifying that all specified items had been removed from use.

[70] VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013.

To remedy the inability to track or find items, the Medical Center implemented an alternative means of tracking product recalls through the patient safety program. In April 2017, the Medical Center asked the PSM to serve as the Recall Coordinator. The PSM reported to the OIG that she implemented medical device or product recalls using the Item Master File, which recorded purchases made by the Medical Center.[71] Although this has functioned as a stop-gap measure, it is an inefficient long-term solution because the Item Master File does not accurately list where the items are located in the Medical Center.

The opportunity to mistakenly use recalled products is heightened when items cannot accurately be accounted for, which in turn can increase risk to patients. Ultimately, the underlying inventory management issues, discussed in the pages that follow, must be corrected for expendable supplies and nonexpendable equipment. In response to the Interim Report's recommendation that, "… the Under Secretary for Health take immediate action to ensure that current stock at the Washington DC, VA Medical Center does not include recalled equipment or supplies," the Medical Center has demonstrated recognition of the significance of the problem and has taken action to address the situation in the short term. No additional recommendation is made on product recalls beyond the recommended actions discussed in Part II of this report to improve the inventory management system.

Recommendations 4–6

Recommendation 4. The Under Secretary for Health specifies criteria under which individual medical centers will conduct wild card Aggregated Reviews for high-frequency patient safety events.

Recommendation 5. The Medical Center Director ensures that routine audits of incident reporting system entries are completed to ascertain that all patient safety events are in the National Center for Patient Safety database as required by VHA policy.

Recommendation 6. The Medical Center Director requires Medical Center oversight committees to follow up and initiate action as necessary on quality assurance matters related to supplies, instruments, or equipment.

[71] VHA Directive 1761, p. 4. The Item Master File is a file within the Integrated Funds Distribution, Control Point Activity, Accounting and Procurement (IFCAP) software system, which contains information on supplies, equipment, vendors, procurement history, and control point activity. The Item Master File links with the request and the procurement history, which allows for a consistent inventory system.

Results (Part II): Service Deficiencies Affecting Patient Care

Although the Medical Center and VISN 5 have taken steps to address the supply chain inventory management issues described in the OIG Interim Report (such as detailing additional personnel to enter data into the authorized inventory system), problems have persisted in getting supplies, instruments, and equipment to patient care areas when and where they are needed. One of the chief causes was the continued inaccuracy and ineffective use of the Medical Center inventory system. The OIG acknowledges that full implementation of an accurate inventory system for a Medical Center of this complexity takes time. However, because of the impact on patient care and the potential waste of government resources, VA and VHA leaders must take immediate action to ensure interim processes are working while dedicating the resources necessary for the Medical Center to fully implement a sustainable, VHA-authorized inventory system.[72] In addition to inventory issues, the OIG identified other factors compromising the ability of the Medical Center to get supplies, instruments, and equipment to providers when and where they need them. These factors included multiple deficiencies across several services in the Medical Center.

Specifically, this section reviews

- The Medical Center continuing supply chain inventory management problems,
- Unsafe storage of clean/sterile supplies,
- Programmatic deficiencies in SPS,
- More than 10,000 open and pending prosthetic consults, and
- Chronic staffing shortages and HR mismanagement that contributed to deficiencies.

Failures in Effective Inventory Management and Availability of Supplies, Instruments, and Equipment Placed Patients at Risk

The Generic Inventory Package (GIP) is the authorized software program used by VHA medical facilities to manage the receipt, distribution, and maintenance of supplies.[73] GIP works by assigning an Item Master File Number to each supply, which helps track its movement from the receiving area to a primary supply area and then to a secondary supply area (generally storage rooms within the clinical areas that use the item). These primary and secondary inventory points

[72] VA Handbook 7002, *Logistics Management Procedures*, July 10, 2009.
[73] VHA Directive 1761(1).

(placement and item data) in GIP, if properly and consistently recorded, identify the quantity of specific supply items in stock and their location.

The Medical Center was required to use the GIP system until early May 2015 when the facility implemented a new inventory system called Catamaran. However, as noted in the Interim Report, Medical Center staff informed the OIG that the Catamaran system was never relied upon. VHA subsequently terminated the Catamaran contract. From January 24 through January 26, 2017 (prior to the OIG receiving the allegations discussed in this report), Policy, Assistance, and Quality (PAQ) staff from the VHA Procurement and Logistics Office, conducted a review of inventory management at the Medical Center. PAQ staff determined that the Medical Center did not have a VHA-authorized inventory system in place.

On March 21, 2017, the Deputy Under Secretary for Health for Operations and Management (DUSHOM) instructed the VISN 5 Director and the Medical Center Director via an emailed memo to provide an action plan addressing the PAQ concerns. Staff were detailed to the Medical Center to take corrective action. Despite those efforts, the April Interim Report provided many examples of how inventory mismanagement and storage, sterilization, and staffing issues contributed to the lack of medical supplies being available where and when they were needed.

Ongoing GIP Implementation Challenges

Following the OIG's Interim Report in April 2017, the Medical Center took steps to implement GIP. The VISN 5 Chief Logistics Officer (CLO) stated that Logistics Service staff worked on cataloguing items with Item Master File numbers and establishing primary and secondary inventory points in GIP. The Acting Medical Center CLO[74] stated that VISN 5 Logistics Service staff detailed to the Medical Center conducted an inventory of all medical supplies, including the on-site warehouse.

During site visits, OIG team members observed the Medical Center inventory practices. The Acting Medical Center CLO and Deputy CLOs and Acting Inventory Manager each had a different estimate of the percentage of items in GIP, ranging from approximately 15–25 percent. In August 2017, the VISN 5 CLO stated that, of a total of 6,694 items in the primary storage areas throughout the Medical Center, 783 (12 percent) were entered into and managed by GIP.

OIG team members found ongoing inaccuracies in the data entered into GIP. In April 2017, OIG staff found discrepancies when comparing physical inventory levels with GIP inventory data and associated purchase orders. For eight of 10 randomly selected items, the physical inventory levels did not match corresponding inventory levels reported in GIP. In some instances, GIP reported more items in stock than were actually present, while in other instances GIP reported

[74] At the Medical Center, the Chief of Logistics Service was the Chief Logistics Officer (CLO). In this report, the OIG uses these terms interchangeably.

fewer items in stock than were physically present. During a follow-up inventory in May, none of the 10 items' physical inventory levels matched the information in GIP. As of July 5, two of the 10 items' physical inventory levels matched the information in GIP. In each instance, OIG staff reviewed the same 10 items in the presence of the Acting Medical Center CLO.

Although a small sample, these discrepancies illustrate that over a four-month period for even a very small number of items, the Medical Center could not reconcile its actual inventory with the data in GIP. As a result, the Medical Center could not rely on the GIP system to identify when supplies were running low or out of stock.

Underutilization of GIP and the Availability of Medical Supplies

Because the Medical Center did not consistently use GIP, it had not collected historical data on utilization rates, so normal stock levels could not be set correctly.[75] When the available quantity of an item falls below or equal to the established reorder point level, GIP can auto-generate a list of items that need to be reordered including required quantities for the items. A miscalculation in setting the stock levels could prevent GIP from automatically generating the list when the Medical Center stock becomes depleted.

The Interim Report described an example of how the inability to ensure that adequate supplies were maintained in secondary supply areas impacted patient care:

- *On March 29, 2017, a nurse reported to the patient safety manager that a patient required oxygen urgently, but there were no oxygen nasal cannulas (tubing that fits into a patient's nose and provides oxygen) on the floor. The nurse was able to use one found on the crash cart, but reported the shortage as a risk to patient safety.*

From August 28–29, 2017, when the OIG returned to the Medical Center to assess supply conditions, nursing staff continued to report outages in secondary supply areas for multiple items (see examples in Table 4).

[75] VHA Directive 1761. Inventory managers establish stock levels "to maintain constant availability of expendable items." For each item stocked, inventory managers are required to define at least three stock levels as follows: (1) the normal stock level, which "represents the largest quantity of an item to be maintained in the inventory point;" (2) the emergency stock level, which "represents the lowest quantity of an item in the inventory point;" and (3) the reorder point level, which "represents the level at which the item is to be reordered." These stock levels are set using the Medical Center's usage history.

Table 4. August 2017 Supply Shortages

Clinical Unit	Supply Shortage
Surgical Intensive Care Unit	Y Alaris Pump IV tubing for blood transfusions
Medical Intensive Care Unit	Nasogastric tubes and telemetry kits
	Glucometer strips (expired)
Oncology Unit	Yellow chemotherapy bins, central lines, tubing for blood transfusions, BD Vacutainers, Luer Locks
Emergency Department	Oxygen nasal cannula tubing

Source: OIG analysis of reported and observed supply shortages

While the OIG did not confirm whether these items were, in fact, out of stock or if the clinical staff had difficulties in locating the items when they were needed, either situation could have been resolved by full utilization of an inventory management system.

In September 2017, the OR ran out of a supply item because of the Medical Center's historic underutilization of GIP.

- *On Friday, September 15, the Medical Center ran out of disposable surgical staplers needed to close surgical incisions. The OR staff borrowed staplers from a nearby private hospital to get through the weekend. A shipment of the staplers reached the Medical Center on Monday, September 18.*

The Deputy CLO who started at the Medical Center in August 2017 stated that supply outages continued to occur because stock levels were set incorrectly.

In addition to patient risks associated with the Medical Center running out of supplies, or being unable to locate them when they are needed, the lack of accurate stock levels can result in urgent reordering, overstocking, and waste of government resources, including the time clinical staff must devote to finding the items.

- *On July 3, 2017, a Prosthetics representative ordered items needed for breast implants (tissue expanders) that arrived and were checked in at the Medical Center loading dock. However, the items were not delivered to the Prosthetics Department and subsequently could not be located. The same items were reordered and delivered on July 7. They were checked in at the loading dock, but subsequently could not be located. Clinical providers repeatedly emailed Logistics and Prosthetics Services staff to ensure the tissue expanders were available for the scheduled procedure. On July 11, the Prosthetics representative was instructed to reorder the needed items a third time and have them shipped overnight for a scheduled surgery. The tissue expanders were received and delivered to the*

Prosthetics Department in time for the surgery. On July 14, the Prosthetics Clinical Supervisor filed a Report of Survey with the VA Police for the missing items.[76]

- *In April 2017, the VISN 5 Logistics Data Analyst placed an order for medical supplies on behalf of the Medical Center. The items were ordered based on information from GIP using the auto-generate orders function. Because GIP on-hand inventory information was inaccurate, some of the items ordered were already in stock at the Medical Center.*
    - *The order included 120 catheterization kits valued at $197.40. The "normal stock level" (15-day) established in GIP was 20 kits and the system showed the Medical Center did not have any in stock. However, a physical inventory inspection found 20 kits in the main clean storage area and 920 kits in the on-site warehouse. The warehouse kits were stacked in a corner and were not easily accessible. Because the Medical Center relied on inaccurate GIP information, they maintained 1,040 catheterization kits, which represent a 26-month supply of the item.*

Although a short-term oversupply would be reasonable considering the Medical Center's inability to determine when a routine item should be reordered, this example illustrates how failure to use an inventory system effectively can result in excessive inventory and incorrect storage.

The OIG also found items stored in incorrect locations and with missing or incomplete barcode labels. The Acting Inventory Manager reported that of about 1,800 items reviewed from the Medical Center GIP, at least 400 items needed to be removed from the system because they were either not located in the warehouse or not used by the Medical Center.

Because information in GIP was not accurate, the Acting Inventory Manager stated Logistics Service staff physically searched for items, checked the list of overflow items stored at the on-site warehouse, and then queried GIP to see if any orders were pending for the item in need. If no items were available, the item was ordered at the assumed required quantity.

Recommendation 7

The OIG's Interim Report recommended that "… the Under Secretary for Health deploy additional logistics staff with in-depth Generic Inventory Package experience to the Washington DC, VA Medical Center until reasonable assurances can be provided that existing logistics staff can maintain an effective inventory management system." VISN 5 detailed Logistics Service

[76] VA Handbook 7002. A Report of Survey is used to document circumstances surrounding government property loss, damage, or destruction occurring because of something other than normal wear and tear.

staff to assist the Medical Center, so the OIG does not repeat that recommendation in this section.

However, the Interim Report also recommended that the Under Secretary for Health implement an effective inventory management system. The Medical Center has more fully implemented GIP, but it has continued to contain inaccurate and unreliable information and be underutilized. Therefore, the OIG makes the following recommendation:

Recommendation 7. The Medical Center Director confirms the full utilization of a VHA-authorized inventory system that contains accurate and reliable information regarding the availability of supplies throughout the Medical Center.[77]

Deficiencies in the Storage of Clean/Sterile Supplies Increased Risks to Patients and to Product Integrity

To advance both patient safety and sound financial management, inventoried items must be secured and maintained in clean conditions. Proper storage of clean/sterile supplies is essential to preventing contamination and patient infections, as well as product deterioration. To maintain supplies properly, clean/sterile storerooms must have stable temperature and humidity, restricted access, weekly shelf-cleaning by Logistics Service staff, and solid bottom shelves at least eight inches from the floor.[78] Logistics Service staff must sign a weekly log stating that the area has been checked for expired supplies, cleanliness, and damage. While Logistics Service staff have responsibility for some specific cleaning tasks in clean/sterile storerooms, the Environmental Management Service (EMS) is responsible for the overall cleanliness of the rooms.

The OIG's Interim Report identified numerous deficiencies in the way staff stored clean/sterile supplies. Specifically, OIG staff inspected 25 satellite clean/sterile storerooms and found

- Eighteen were dirty;
- Five mixed clean with dirty equipment or supplies;
- Eight contained supply racks lacking solid bottom shelves as required to reduce cross-contamination from the floor;
- Seventeen lacked a method to monitor pressure, temperature, and humidity;
- Five were cluttered; and
- Five improperly served multiple purposes such as office or patient care space and lacked security and appropriate environmental controls.

[77] VHA Directive 1761(1) and VHA Handbook, 7002. GIP is the VHA-authorized inventory system.
[78] VHA Directive 1761(1), p. G1.

Under these conditions, there was no assurance that sterile supplies maintained their integrity. In interviews following the release of the Interim Report, EMS leaders stated that the primary reason that clean/sterile storerooms were dirty was because the Medical Center did not have the staff to clean them. The EMS Chief reported having difficulty hiring and retaining qualified staff. In addition, the Medical Center did not routinely include clean/sterile storerooms in its Environment of Care (EOC) rounds.[79] If included, inspections would have provided consistent oversight of these areas by additional personnel.

While EMS is responsible for cleaning the storeroom floors, Logistics Service, which was also significantly understaffed in FY 2017, is responsible for cleaning the storage bins and for monitoring temperature and humidity in areas where expendable supplies are stored. VISN 5 knew of staffing shortages in EMS in early FY 2017, and was aware of staffing shortages in Logistics Service at the Medical Center as early as 2014, based on an external consultant's report.

The OIG inspected clean/sterile storerooms on multiple occasions to assess compliance with VHA policy requirements.[80] Review categories included the following:[81]

- **Cleanliness**—as evidenced by clean floors, walls, storage bins, and ventilation vents; weekly cleaning logs in storage areas; and lack of clutter
- **Infection Prevention**—as evidenced by records of temperature and humidity monitoring; floors free of storage containers or supplies; separation of clean/sterile supplies and dirty items; restricted traffic; solid bottom storage shelf; and storage areas not used as an office or patient care space
- **Supply Management**—as evidenced by clinical supplies being managed and replenished by Logistics or other designated staff, not clinical staff

OIG inspections that followed the Interim Report release are summarized in Table 5.

[79] VHA Directive 1608, *Comprehensive Environment of Care (CEOC) Programs*, February 1, 2016. VHA requires Medical Center leaders to ensure the medical facility is routinely inspected, which is referred to as Environment of Care rounds.

[80] VHA Directive 1608.

[81] The OIG selected these parameters for categorization based on the subject matter expertise of team members and their experience conducting EOC reviews at VA medical facilities.

Table 5. Number of Clean/Sterile Storerooms Meeting Selected Criteria

Criteria	April 25 Inspection	June 27 Inspection	August 28–29 Inspection
Cleanliness	19 of 29	22 of 30	21 of 27
Infection Prevention	8 of 29	15 of 30	20 of 27
Supply Management	9 of 29	27 of 30	25 of 27

Source: OIG observations

OIG staff noted improvements in the cleanliness of storage rooms. The Medical Center entered into a contract with a commercial cleaning service on June 11, 2017, to supplement the Medical Center EMS staff. In August 2017, cleanliness had improved throughout the Medical Center. Staff interviewed stated that EMS services and accountability had improved since OIG's initial visit in March 2017. There were, however, six of the 27 clean/sterile storerooms in August that did not meet the selected criteria for cleanliness. In addition, a little over one-fourth of the clean/sterile storerooms did not meet selected infection prevention criteria.

As of September 2017, the Acting Human Resources Director reported to the OIG that of the 147 authorized EMS positions, 138 were filled (a five percent vacancy rate).

Recommendation 8

Because infection prevention measures had not been fully implemented despite improvements in cleanliness in clean/sterile storerooms since the Interim Report, the OIG reiterates its recommendation:

Recommendation 8. The Medical Center Director makes certain that the environmental integrity of clean/sterile storerooms complies with VHA policy.

Delays and Ineffective Sterilization Disrupted SPS Reprocessing of Reusable Medical Instruments and Equipment

After publication of the Interim Report, the OIG identified multiple deficiencies in the Medical Center SPS that prevented healthcare providers from accessing surgical instruments when needed.[82] The OIG inspected SPS on six different occasions between March 2017 and

[82] SPS is responsible for appropriately reprocessing (cleaning) instruments or equipment that come into contact with sterile body cavities or mucous membranes (known as critical or semi-critical reusable medical equipment). SPS responsibilities begin when used items are collected for processing and end when properly cleaned instruments or equipment reach the patient.

August 2017. On each occasion, the OIG found evidence of persistent failures in SPS that limited the ability of the Medical Center to provide care to veterans.

Problems in SPS were not new. Prior reviews shared with the Medical Center, VISN, and VHACO consistently revealed deficiencies in SPS processes and procedures, staffing and leadership, and environment of care that dated back to at least 2015. These included the following National Program Office for Sterile Processing (NPOSP) reports.

- **April 2015**: There were 53 corrective actions related to decontamination, sterilization, high-level disinfection,[83] and storage of reprocessed reusable medical equipment (RME).[84]
- **September 2015**: Of the 53 previously identified corrective actions, 24 were not addressed.
- **October 2016:** There were 140 corrective actions related to some repeat findings, staffing levels and competencies, SOPs, compliance with manufacturers' instructions for use, the semi-critical and critical RME master inventory list, and environmental conditions.

When asked why these conditions remained uncorrected for so long, current SPS managers cited chronic understaffing of SPS and difficulties retaining qualified personnel.

OIG Inspection Results

The OIG identified many of the same conditions as the 2015 and 2016 NPOSP reviews during an initial March 2017 site inspection, including SPS using expired supplies and experiencing supply shortages. Subsequent visits revealed the following:

- Discolored or broken instruments reaching clinical areas
- Lack of a clear process for acquiring and reprocessing new instruments
- Incomplete surgical trays reaching OR
- Improper tracking and reprocessing procedures for loaner instruments
- Missing or expired SPS supplies
- Failure to follow manufacturer's instructions for reprocessing instruments and to keep manufacturer's instructions in SPS readily available for staff reference to facilitate compliance

[83] High-level disinfection is the process of complete elimination of all microorganisms on a device using chemical solutions.

[84] The problem with the storage of reprocessed RME was primarily related to using one room for clean and dirty medical equipment.

- Inadequate documenting of staff competencies to perform particular processes
- Not consistently maintaining separation of clean from dirty items in satellite reprocessing areas

Discolored or Broken Instruments Reaching Clinical Areas

Items stained, discolored, and broken were seen being prepared for sterilization, rather than recleaned or repaired. During inspections of SPS, OIG staff noted that some discolored instruments were sent to the dental clinic or were being prepared for sterilization. The OIG did not find evidence, though, that they were used on patients. It was unclear whether the discoloration on the instruments resulted from debris or hard water staining. However, had SPS performed routine visual inspections prior to sterilizing instruments and returning them to clinical areas, SPS personnel should have detected the discoloration. They could have then removed the instrument from service and taken action to address the discoloration before returning the instruments to clinical areas.

In November 2017, the OIG received a complaint about cancellation of nine surgeries at the Medical Center.[85] The OIG confirmed the cancellations and that the Medical Center had reported to VHACO that spotting and discoloration were found on some instruments.

A contractor examined 8,931 pieces of equipment and instruments over a two-day period. The contractor reported finding rust on about 30 instruments; those items were polished and returned to service. The Medical Center conducted water quality tests and reported that the tests did not reveal concerns. The Medical Center also reported taking steps to ensure patient safety and attested to NPOSP staff who conducted an assessment of the discolored instruments that "all instruments will be rust, stain, damage and bioburden free." The Medical Center further stated that a quality assurance process would be implemented requiring OR staff to attest that all instruments had no evidence of rust, staining, or discoloration.

Lack of a Clear Process for Acquiring and Reprocessing New Instruments

The same contractor continued to inspect instruments and equipment for the Medical Center during November 2017, and recommended replacing 216 instruments of 8,931 inspected.

[85] The November complaint was from an anonymous source and included concerns that improperly sterilized instruments infected patients with Hepatitis C. Medical Center leaders denied knowledge of patients having been infected with Hepatitis C associated with improper sterilization. To determine the merits of this allegation, OIG physicians reviewed the medical records of patients with newly diagnosed Hepatitis C infections who had previously received a surgical procedure at the Medical Center between April 1, 2016, and November 1, 2017. The OIG identified one patient who had an OR-based surgical procedure and subsequently tested newly positive for Hepatitis C. The patient's surgical procedure was 364 days prior to his conversion to a positive Hepatitis C test. The patient had a negative Hepatitis test in 2011; he had multiple risk factors that could have increased the likelihood of acquiring Hepatitis C. Therefore, the OIG could not state with certainty the cause of the patient's Hepatitis C infection.

Historically, staff had reported difficulties in replacing surgical instruments when needed, which may have contributed to the contractor's findings. Interviews and email communications between and among Surgery Service, SPS, and the OR staff about broken equipment or instruments indicated substantial confusion about who was responsible for initiating and approving orders for new or replacement instruments. In addition, email communications and meeting minutes reflected that staff were told the Medical Center had no resources to purchase new instruments.

Even when new instruments were purchased, they could not always be reprocessed appropriately nor were they stored properly.

- *In October 2015, the Medical Center purchased 40 ENT [Ear, Nose, Throat] endoscopes, at a total cost of approximately $350,000. While the minutes from a March 2016 meeting of an RME committee stated that the ENT endoscopes had been purchased and delivered, SPS staff told the OIG team that a chronic shortage of trained SPS technicians prevented the endoscopes from being reprocessed for use. The endoscopes had been stored in various locations, including the ENT clinic, but on May 9, 2017, OIG inspectors found them in carts in the SPS sterile area covered by an unsterile blanket.*

Because SPS staffing limited the Medical Center's ability to put more equipment into service, clinicians had fewer instruments available to them if an item needed repair or was in use by another healthcare provider.

Incomplete Surgical Trays Reaching the Operating Room

In addition to stained or broken instruments, OIG staff were told that dental and vascular surgical sets were returned to SPS with missing items or instruments, which resulted in incomplete surgical trays being processed and returned to the OR. In November 2016, email communications between SPS and OR staff indicated that SPS had "hundreds of instruments for purchase to prioritize completing the missing trays." Further, "[m]issing instruments and incomplete trays have been a perennial patient access and safety concern in the medical center." As of August 2017, the Medical Center reported ordering 39 new surgical instrument sets, with expenditures from all sets totaling $1,026,241.

SPS staff is responsible for checking that all items are included in the surgical trays and ensuring cleanliness and functionality before packaging.[86] A quality assurance program must be in place that monitors whether surgical trays leaving SPS are complete and instruments are in proper

[86] VHA Directive 1116(2).

working order. During OIG site visits, SPS managers admitted they did not have an effective quality assurance program in place.

Improper Tracking and Reprocessing of Loaner Instruments

When medical center staff know in advance that they do not have the instruments they need for a certain procedure, they may borrow specialized instruments from vendors or other sources. This is an acceptable process when it occurs in advance of a scheduled procedure. It should not be a routine practice for staff to leave the OR to borrow instruments (loaner instruments) from nearby facilities during a procedure or immediately prior to it.

Loaner instruments are considered nonsterile and must be received, inspected, recorded, decontaminated, and sterilized in SPS. VHA policy states that loaner instruments must be received at least 48 hours prior to surgery to ensure that the instruments can be appropriately reprocessed prior to the procedure.[87] The Medical Center had developed an SOP that extended the 48 hours to a two-week time frame for educating staff and confirming current manufacturer's instructions. Because the loaner instruments are "new" to the Medical Center, SPS must also have a copy of the manufacturer's instructions, have time to develop an SOP for cleaning them, and train staff on the SOP before they are put in use. An electronic loaner set tracking system is available for monitoring and documenting loaned instruments.

The October 2016 NPOSP review identified that the Medical Center did not have a policy designating responsibility among all individuals involved in the loaner equipment process and recommended that the Medical Center establish one. In response to an April 2017 OIG request, Medical Center personnel provided a draft policy dated December 2016 and signed by then Medical Center Director Hawkins. As the RME committee had not reviewed the draft loaner instrument policy, it was not yet final and Medical Center staff could not be held accountable for failing to follow it. Although the draft policy included a reference to the use of a specific electronic loaner instrument tracking system, the Medical Center reported to the VISN in April 2017 that the electronic tracking system had not been implemented and that its tracking of loaner instruments was inconsistent.

- *SPS received a loaner Stryker Orthopedics instrument set in August 2017 for use in a surgical procedure. The SPS Chief had developed a process to allow two weeks for the development of SOPs and competencies for new instruments, in order to conduct training before the instruments were used. Because of the short time frame for the scheduled surgery, SPS could not fully train staff and follow this process. The patient underwent surgery without complications.*

[87] VHA Directive 1116(2).

As of August 2017, the electronic loaner instrument tracking system had been purchased and implemented. However, access was not available for several reasons: An information security issue was reported; staff had not completed a business justification needed for approval to access the non-VA system; and the vendor had not been paid. Instead of an electronic system, SPS staff were using a paper log to track loaner trays. However, the NPOSP staff who were routinely being detailed to the Medical Center in 2017 checked random sections of the paper log book and found incomplete documentation and loaner instrument tracking. The Medical Center could not ensure that all loaner instruments had been reprocessed in accordance with VHA policy. As of August 2017, the Medical Center was unable to provide the OIG with a signed and approved final loaner policy.

Missing or Expired SPS Supplies

At times, SPS staff did not have supplies for the performance of their duties. The OIG's Interim Report outlined SPS staff use of expired chemical indicator strips that confirm when an item has been sterilized. The OIG found that the Medical Center could not determine whether the expired indicators had been used for some of the 396 items sterilized in the Medical Center between the date of the strips' expiration (February 28, 2017) and the date staff discovered the expired strips and removed them from use (March 16, 2017). The Medical Center also experienced a shortage of mobile insulation wands, which are used to conduct "leak testing" in order to detect microscopic pinholes in the insulation of electrosurgical instruments. Twenty patients underwent procedures between February 28 and March 16, 2017, using laparoscopes that had not been leak-tested.

The Medical Center Infection Control nurses and a physician conducted EHR reviews of those patients potentially impacted by the chemical indicator or leak-test deficits and did not identify adverse clinical outcomes such as postoperative surgical site infections. This was confirmed by an OIG independent review. However, the Medical Center's inability to test for leaks in the insulation of electrosurgical instruments unnecessarily placed patients at risk for burns or infection during the 20 laparoscopies.

SPS continued to experience supply shortages as late as August 2017. On August 29, 2017, the Medical Center reported to the OIG that an item critical to the sterilization process, Bowie Dick chemical indicators used to test sterilizers' air removal system, were out of stock. No surgical cases were canceled because SPS personnel found "a few" in a drawer that could be used until the supply item arrived the following day.

Staff Failing to Follow and Keep Manufacturer's Instructions Readily Accessible for Reprocessing Instruments

Manufacturer's instructions describing how to clean medical equipment and instruments must be maintained in SPS where instruments are reprocessed, so that directions are readily available to employees. Staff must also routinely update SOPs for cleaning medical instruments and

equipment to remain consistent with the manufacturer's instructions. The Medical Center did not have manufacturer's instructions for use and related SOPs available where cleaning was conducted for staff reference as required by VHA policy.

To ensure pertinent manufacturer's instructions are available, the Medical Center must maintain a master list of RME in use. SPS technicians and leaders are responsible for completing and updating the master list. Staff use the list of equipment to verify that SOPs are available for each item in use at the Medical Center, and that staff have the appropriate competencies for the item.

Without proper directions, staff cannot be sure they are complying with both manufacturer's instructions and Medical Center procedures. In May 2017, OIG staff directly observed conditions in SPS and found the following:

- *The ultrasonic cleaner (a device that uses ultrasound waves to clean instruments by cavitation) was always set for 10 minutes, when some instruments required a different amount of time.*[88] *While the instruments still undergo sterilization, it is important that debris be removed prior to the sterilization process for the process to work as intended.*
- *Only one set of cleaning instructions was available, which was for dental equipment, in a room where nondental equipment was being reprocessed.*
- *The SPS technician deviated from the manufacturer's instructions for a particular instrument in the amount of detergent-to-water ratio required to clean the instruments and the manufacturer's instructions were not in the room.*

The SPS technician's departure from manufacturer's instructions in the amount of detergent-to-water ratio underscores the importance of verifying technicians' competencies to clean specific instruments.

Inadequate Documenting of SPS Staff Competencies

Because of the complex nature of SPS work, technicians must have their competencies to reprocess equipment documented. The OIG noted during multiple site visits, that SPS staff competencies were not completed or were outdated. A high-risk SPS activity is defined through a required annual assessment by the Medical Center.[89]

[88] "Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)," Centers for Disease Control and Prevention, accessed January 8, 2018, https://www.cdc.gov/infectioncontrol/guidelines/disinfection/cleaning.html. "Thorough cleaning is required before high-level disinfections and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes."

[89] VHA Directive 1116(2).

On March 30, 2017, the OIG requested and received the competency grid for eight SPS technicians that included documentation for 164 equipment/instruments and processes. Approximately 75 percent of the items (126 of 164) were considered moderate to high risk that would require a shorter interval for reevaluating initial competencies. The OIG identified multiple documentation deficiencies:

- Twenty-six of 126 moderate to high-risk competencies for a long-term senior staff member with broad reprocessing responsibilities were expired or lacked dates of completion.
- Four of eight SPS staff members lacked documentation of required training.
- Twenty-one of the 164 instrument groups lacked risk assessments.[90]
- Competencies were not consistently updated with manufacturer's instructions.

In addition to the inadequate documentation of competency issues, the Acting SPS Chief and the Acting RME nurse educator provided conflicting information regarding whether staff reprocessing certain instruments had the right competencies. (In addition to the SPS technician deficiencies noted above, OIG inspectors observed a staff member working in the gastrointestinal (GI) satellite reprocessing area who did not have documentation of all appropriate updated competencies listed.)[91]

The OIG communicated its preliminary findings to the Medical Center Director at the time of its initial March 2017 visit. Three months later, SPS problems remained unresolved. While OIG was on-site the week of June 26, 2017, the Medical Center could not verify that SOPs were updated with the most recent manufacturer's instructions, and therefore could not confirm that the competencies of technicians were being evaluated against the most current procedure for cleaning instruments. Observed deviations from proper reprocessing procedures, coupled with outdated or missing documentation of staff competencies, contributed to an environment that perpetuated patient risk and reflected the Medical Center's inability to rapidly correct identified deficiencies.

OIG staff conducted another inspection in August 2017. At that time, documentation of risk assessments and staff competencies had improved, but was still incomplete. Additionally, competencies existed for 146 of the 164 equipment/instruments or processes, and risk assessments were up-to-date on 124 of the instruments.

[90] Risk assessments determine whether cleaning a particular instrument is likely to cause harm to the handler or requires special care. High-risk instruments require competencies to be updated annually.

[91] A satellite reprocessing area is any area outside of SPS where reprocessing is performed such as ENT, Bronchoscopy, and GI clinics.

Not Consistently Maintaining Separation of Clean from Dirty Items in Satellite Reprocessing Areas

The OIG did not conduct an in-depth review of the primary SPS reprocessing area because the environmental deficiencies have already been well-documented through previous NPOSP site visits and the Medical Center has taken steps to address them.[92]

OIG inspections focused on satellite reprocessing areas. VHA requires the Chief of SPS to ensure that there are separate areas for different phases of reprocessing (such as decontamination, preparation, and packing) and that manufacturer's instructions and related SOPs are available. VHA policy also requires that access to reprocessing areas be secured.

The following deficiencies were found during inspections of the ENT and bronchoscopy suite satellite reprocessing areas:

- *The ENT endoscope reprocessing area did not separate the decontamination area (where dirty items are manually cleaned) from other reprocessing areas. According to VHA policy, "the Decontamination Area must be physically separated from all other areas."* [93] *The nurse manager for ambulatory clinics authorized this deviation in 2013 because of space constraints. In addition, access to the reprocessing area was not secured.*
- *The bronchoscopy suite (where the bronchoscopes were stored) was not secured. The OIG reported these conditions to bronchoscopy suite staff. On reinspection approximately one month later, the suite was still unlocked. After inspectors inquired about the status of efforts to secure the suite, the Medical Center installed a lock while the inspectors were on-site.*

As of July 2017, the Medical Center had resolved the problems in ENT. Dirty ENT instruments and endoscopes were precleaned in the ENT procedure room and placed in red bins. The bins were placed in closed transport carts that were transported by SPS staff to the primary SPS decontamination area where they were reprocessed. The ENT room had a key pad lock in place to restrict access to authorized staff.

[92] Medical Center leaders sought funds and approval from the VISN and capital investment planning personnel for renovations to SPS as early as 2013, with repeated attempts throughout 2015 and early 2016. In a March 2016 memo, the Medical Center Director informed the Acting VISN Director that "Local FMS [Fiscal Management Service] and SPS staff have aggressively worked to correct many deficiencies. In spite of these efforts, risk remains present and cannot be further mitigated without renovation." VISN 5 staff advised the Medical Center to develop an interim plan to address some NPOSP critical concerns that included the use of mobile SPS units. Two mobile units were delivered in late May 2017 but were not functional until July 2017.

[93] VHA Directive 1116(2).

As SPS supply shortages will be addressed with improved implementation of a VHA-authorized inventory management program as recommended elsewhere in this report, the OIG does not make a recommendation specific to SPS supplies. Because there are other deficiencies remaining in SPS that affected staff's ability to get care providers usable supplies, instruments, or equipment when needed, the OIG makes the following recommendations:[94]

Recommendations 9–16

Recommendation 9. The Medical Center Director ensures there are clearly defined and effective procedures for replacing missing or broken instruments, and that staff responsible for this function have been educated on the process.

Recommendation 10: The Medical Center Director confirms that clearly defined and effective procedures address the disposition of discolored instruments during reprocessing and that staff responsible for this function have been educated on the process.

Recommendation 11. The Medical Center Director ensures that the Sterile Processing Service (SPS) implements a quality assurance program to verify the cleanliness, functionality, and completeness of instrument sets prior to their reaching clinical areas.

Recommendation 12. The Medical Center Director makes certain that SPS and OR personnel comply with policies and procedures for the proper reprocessing of loaner instruments and trays.

Recommendation 13. The Medical Center Director verifies that SPS managers maintain an accurate Master List for reusable medical equipment and file copies of manufacturer's instructions as required by VHA policy.

Recommendation 14. The Medical Center Director ensures that the SPS maintains updated and readily accessible standard operating procedures for all instruments and equipment within SPS and its satellite areas in accordance with VHA policy.

Recommendation 15. The Medical Center Director verifies that all SPS employees have appropriate, updated competencies and a demonstrated proficiency to perform their assigned duties.

Recommendation 16. The VISN 5 Director secures adequate space and funding for the Medical Center satellite reprocessing areas, which includes separate decontamination, processing, and packaging areas in accordance with VHA SPS policies.

[94] The OIG determined a high staff vacancy rate and weaknesses in leadership contributed to these recurring problems, which are discussed in other sections of this report.

More Than 10,000 Open and Pending Prosthetic Consults Affected Patient Care

VHA requires that quality patient care be provided by furnishing properly prescribed prosthetic equipment, sensory aids, and devices in an economical and timely manner.[95] To order a prosthetic appliance or implant,[96] a Medical Center provider must initiate and submit a consult (a request for an item that allows for subsequent tracking) in the EHR to the Prosthetics Service.[97]

A prosthetic consult is considered "closed" when a patient receives an in-stock item, a purchasing agent ships an in-stock item to the patient, or a purchasing agent places an order with a vendor for a nonstocked item to be shipped directly to the patient. A prosthetic consult is placed in a "pending" status if other actions must be taken before the consult can be completed. For example, if the patient needs to be fitted for orthotics before an order can be placed, the consult is marked pending if an appointment has been made for the fitting. Such actions should be documented in the prosthetic consult to allow for tracking through completion. VHA business practice guidelines for prosthetic consult management states that pending prosthetic consults "must be reviewed at least weekly by the Chief, [Prosthetic and Sensory Aids Services (PSAS)] and the Prosthetic employee responsible for completing that consult." VHA requires the closure of pending prosthetic consults upon the earlier of 45 working days or 60 calendar days.

OIG staff identified 10,904 prosthetic consults that were open or pending as of March 31, 2017.[98] There were 1,621 prosthetic consults that could be matched with purchase order data, indicating that the appliance had been ordered and therefore the consults should have been closed. From the remaining 9,283, OIG staff conducted a detailed analysis of 472 consults that were determined to present a higher risk of harm to veterans who had to wait more than 45 working days for the prosthetic appliance. The OIG did not identify adverse clinical outcomes for the 472 veterans.

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[95] VHA Directive 1173.

[96] VHA Handbook 1173.1. Prosthetic appliances include "[all] aids, devices, parts or accessories which patients require to replace, support, or substitute for impaired or missing anatomical parts of the body. The items include artificial limbs, terminal devices, stump socks, braces, hearing aids and batteries, cosmetic facial or body restorations, optical devices, manual or motorized wheelchairs, orthopedic shoes, and similar items."

[97] The Prosthetics Service is responsible for ordering prosthetic items that cost less than $3,500. Orders exceeding that amount must be placed through a VHA Contracting Official.

[98] The average time elapsed for all open or pending prosthetic consults was 95 calendar days. Of the 10,904 prosthetic consults, 6,385 had been open or pending for 60 calendar days or more, which does not conform to the VHA 60-day closure requirement. Although these numbers are indicative of process failures, the numbers do not necessarily measure the time the veteran waited for a device for at least two reasons: First, the impact to the veteran was continuing as of March 31 if the veteran had not received the device. Second, some of the consults had been addressed, but were not closed in the consult software package.

The remaining prosthetic consults included, among other items, the following:[99]

- 1,285 home Continuous Positive Airway Pressure machines
- 1,036 splints or braces (such as elastic ankle braces, air casts, carpal tunnel wrist braces, and similar devices)
- 633 shoes and accessories (diabetic shoes, sole inserts, heel risers, and similar devices)
- 578 home blood pressure monitors
- 467 compression stockings, sleeves, or gloves
- 393 orthotics
- 237 home Transcutaneous Electrical Nerve Stimulation devices
- 228 canes
- 222 wheelchairs

OIG inspectors conducted follow-up interviews in August 2017 to evaluate Medical Center efforts to resolve the large number of open and pending consults, and obtained Medical Center data regarding delays.

Medical Center staff told OIG inspectors in August 2017 that as the Medical Center reduced the number of open and pending consults it was confirmed that some veterans were waiting extended periods of time for items such as knee braces. A staff member stated that in some instances, the pending or open consults were explained by clerical failures to close the consult when the veteran received the device. In addition, some of the consults were duplicate requests for previously unfilled orders.

The OIG determined that due to the large number of consults, some patients experienced delays in receiving their prosthetic appliances. OIG inspectors identified an example of a patient whose primary care provider entered multiple consults for a new artificial leg without resolution of the consult.

- *On a day in 2016 (Day 1),[100] a patient requested a new artificial leg because of pain in the area where the current device attached to his stump. According to the EHR, his care provider placed a consult to Rehabilitation Medicine–Amputation*

[99] This list does not sum because it includes major categories of identified prosthetic devices rather than every individual item outside major categories.

[100] Throughout this report, dates and patient identifiers have been removed to ensure compliance with privacy mandates.

Outpatient Clinic to evaluate the patient's complaints. On Day 36, the patient's provider placed two prosthetic consults—one for a wheelchair and the other to address the patient's prosthesis and a related wound. Consults for an evaluation for the artificial leg were resubmitted on Day 68 and Day 117. On Day 229, a provider's note in the EHR indicated that the patient had problems reaching the prosthetic stump clinic. On Day 364, the consult for a prosthetic leg evaluation remained unfulfilled. A prosthetic consult entry on that day stated that the patient had not been seen by the amputee clinic team and that the patient had not been scheduled for an appointment with the team. The patient subsequently moved out of the area without receiving the device. The OIG's review of the patient's EHR showed that on or about Day 417, the patient received a replacement artificial leg from a VA facility in another state.

The patient's primary care provider resubmitted consults in an effort to get the original consult addressed. The primary care provider did not directly contact the Prosthetics Service, or make other efforts to get the patient his prosthetic device. The EHR contained no documentation as to why the Medical Center Prosthetics Service did not supply the patient with a prosthetic limb.

OIG staff identified eight additional consults for patients needing prosthetic limbs where the status indicated "pending." The OIG determined that seven of these patients had either received the prostheses by the time of the OIG analysis or had canceled the request. For these seven patients, between two and 169 days elapsed from the time the consult was placed until the prosthetic appliance was received or the request was canceled. On average, 79 calendar days elapsed, with six patients waiting more than 55 days or more and one waiting two days. OIG physicians reviewed the EHR for each of these patients and found no clinically significant adverse outcomes. Documentation for the remaining patient case was insufficient for the OIG to determine whether the patient received the appliance. The Medical Center has attempted to follow up with the patient.

While the OIG did not identify that delays in obtaining prosthetic limbs resulted in adverse clinical outcomes, long wait times for receiving prosthetic limbs or associated accessories can significantly affect a patient's quality of life.[101] The large number of open or pending prosthetic consults and the fact that resolution of those consults remained in progress made it impossible for the OIG to fully evaluate the delays experienced by veterans. The OIG's analysis of consults relating to prosthetic limbs included 32 amputee veterans with pending consults for various standard accessories (not customized) including gel liners, wheelchair cushions, exercise stools, stump socks, and similar items. An average of 81 calendar days elapsed before the items were

[101] In addition, the need to make repeated requests for fulfillment can result in unnecessary appointments with clinical staff, which impacts access to care for all veterans served at the Medical Center.

ordered, which exceeded the 60 calendar day closure requirement. None of the records associated with these 32 consults showed evidence that preordering actions were required (such as a custom fitting) that might explain the delay in ordering.

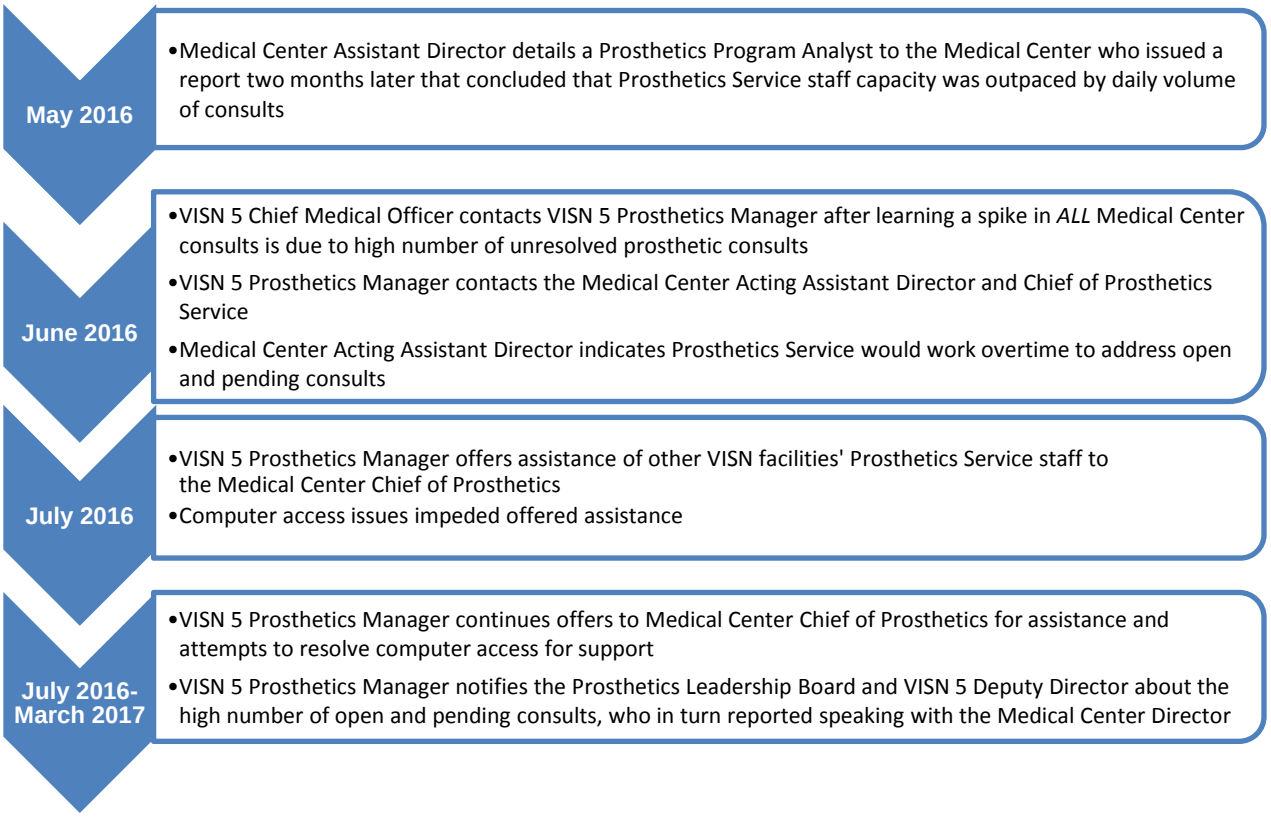
How the High Number of Open and Pending Consults Occurred

To determine how the Medical Center accumulated so many open and pending consults for prosthetic devices, the OIG reviewed the history of prosthetic consult management at the Medical Center. The Medical Center reported that the number of open or pending prosthetic consults grew because of challenges, among others, in leadership and fiscal management.

Leadership Awareness and Actions

Medical Center leaders became aware of the increasing number of open and pending prosthetic consults in spring 2016. Figure 2 outlines actions and communications of Medical Center and VISN 5 leaders between May 2016 and March 2017.

Figure 2. Medical Center and VISN 5 Leaders' Actions and Communications Regarding Prosthetic Consults May 2016–March 2017



Source: OIG analysis of Medical Center and VISN 5 emails and OIG 2017 interviews

Although the VISN 5 Prosthetics Manager (the manager) began arranging for the assistance of other Prosthetics Service personnel within VISN 5 to assist the Medical Center in July 2016, the manager told OIG inspectors that the Medical Center Chief of Prosthetics did not complete the required administrative steps (issuance of purchase cards and computer access) to enable these individuals to assist. The manager reported elevating the issue to VISN 5 Deputy Director Richardson, who reported back to the manager that he spoke with Medical Center Director Hawkins about the issue.[102]

The manager indicated that as late as March 3, 2017, at least four of the Medical Center purchasing agents did not have access to the software necessary to place orders on their own computers. The manager raised this matter for resolution with the Acting Medical Center Associate Director and the Medical Center Assistant Director. During an August 2017 interview, the OIG confirmed that purchasing staff who previously lacked access to essential software had been granted access. In addition, OIG inspectors were told that productivity had improved such that employees were processing an average of 25 to 30 purchase orders per day, whereas some poorly producing employees were previously issuing only five to six purchase orders per day.

The high number of open and pending prosthetic consults persisted and grew in large part due to lack of effective leadership in the Medical Center, as reflected by leaders' awareness of the condition and the failure to address it effectively from May 2016 onward. The Assistant Medical Center Director reported keeping Mr. Hawkins and other leaders apprised of the prosthetic consult issue and of making efforts to resolve it, including working to fill vacancies in the Prosthetics Service and taking disciplinary action against relevant employees. The Assistant Medical Center Director also stated to OIG inspectors that budgetary concerns precluded efforts to hire staff at the end of FY 2016 and that after the start of the new fiscal year, HR dysfunction delayed hiring actions.

As of September 2017, the Acting Human Resource Director reported to the OIG that of the 22 authorized Prosthetics Service positions, 20 were filled (nine percent vacancy rate).

Fiscal Service Management

The OIG determined that the Medical Center Fiscal Service also contributed to the increasing number of open and pending prosthetic consults by suspending prosthetics purchasing on multiple occasions in FY 2016. The Medical Center Chief of Fiscal Service is responsible for providing Prosthetics Service staff with a series of transaction and purchase order numbers used

[102] For this report, the OIG has not listed the names of VA or VHA leaders who held positions below a GS-15 level (or its equivalent).

to order prosthetic appliances in the VistA computing system.[103] From approximately December 19–31, 2015, purchasing agents were unable to place orders because the VistA transaction numbering series for the applicable fund control point reached its limit and Fiscal Service lacked the proficiency needed to quickly resolve the issue. This issue recurred for another eight days in March 2016.

Another period of suspension occurred from September 28, 2016, through October 6, 2016, when the Medical Center stopped all purchasing in order to facilitate the routine process of reconciling accounts at the end of the fiscal year. VISN 5 staff explained that the Medical Center was unique among its peers in the VISN by not permitting purchases to occur until funding was placed into the fund control points at the start of the fiscal year. Other VISN facilities avoided cessation in purchasing by permitting a small amount of negative balance purchasing to occur at the start of the year, pending the actual delivery of funds.

Because of the large number of open and pending prosthetic consults, an inability to place new orders during periods of suspension, and a steady number of new daily consults, the Prosthetics Service could not catch up, and the large number of open and pending consults persisted.

On April 7, 2017, the Medical Center Chief of Prosthetics was detailed to another position. As of June 29, 2017, there were 8,218 prosthetic consults open or pending longer than five days.

Remediation Actions

To resolve the open and pending consults, the Acting Medical Center Assistant Director reported on efforts to hire staff, redesign the organizational structure, claim 2,000 square feet of warehouse space for inventory, and work to develop a walk-in clinic. In addition, nine purchasing agents had been assigned from across VHA to assist with resolving open and pending prosthetic consults.

On August 29, 2017, OIG staff spoke with the Acting Chief of Prosthetics who confirmed that through the use of additional staffing, the Medical Center had been able to reduce the number of prosthetic consults to approximately 6,130, of which 3,800 are more than 30 days old. Also in August, the Medical Center chartered an Administrative Investigative Board to determine accountability for the failures identified within the Prosthetics Service.

[103] The Veterans Information Systems and Technology Architecture (VistA), is the computer system that VHA uses to support its clinical and administrative functions. It is composed of integrated clinical, infrastructure, and financial/administrative software applications. VistA requires a unique transaction number and a unique purchase order number for each prosthetic order.

Recommendations 17–18

Because the Medical Center still had more than 6,000 open or pending prosthetic consults as of August 2017, the OIG makes the following recommendations:

Recommendation 17. The VISN 5 Director makes certain that the Medical Center Director resolves open and pending prosthetic consults and implements a plan to address future prosthetic consults in accordance with VHA policy.

Recommendation 18. The Medical Center Director ensures the revision of Medical Center Fiscal Service practices to eliminate unnecessary cessations of prosthetic device purchasing, including at fiscal year-end.

Inadequate Staffing and Human Resource Management Deficiencies Contributed to Failures across Multiple Services

As previously discussed, Medical Center personnel often attributed deficiencies in Logistics Service and SPS to chronic understaffing. To obtain additional staff, Medical Center policy specifies that Service Chiefs must determine the minimum number of positions needed to perform the functions of their services and submit requests for new positions or changes in the grade of already approved positions to the Resource Management Committee (RMC).[104] The Associate Director of the Medical Center chairs the RMC Committee, which makes recommendations to the Medical Center Director regarding approval or disapproval of these requests, based in part on budgetary considerations. The Medical Center HR is responsible for executing actual hiring actions.

The OIG determined that Logistics Service and SPS had experienced historically high vacancy rates. A number of factors contributed to these rates, including a failure to maintain accurate data on the numbers of authorized positions throughout the Medical Center; the RMC not performing its duties in accordance with Medical Center policy; and HR not completing hiring actions appropriately. The Acting Medical Center Director Lawrence Connell has taken a number of actions to identify and fill critical staff vacancies that remained open or understaffed for long periods.

Historically High Vacancy Rates in Logistics Service and SPS

The Medical Center had experienced high vacancy rates in Logistics Service and SPS as early as 2014.

[104] MCM-00C-15, *Resource Management Committee*, (2013). This is the Medical Center policy that outlines Service Chief, Human Resources Services, and RMC functions and responsibilities.

Logistics Service

In 2014, VISN 5 engaged an external consultant to study Logistics Service operations within its facilities (2014 Logistics Study). Of the 12 authorized positions for expendable supply management, three positions were vacant. The 2014 Logistics Study also cited a 50 percent vacancy rate in Medical Center Logistics Service staff positions responsible for nonexpendable property management.

The Medical Center Deputy CLO position remained vacant from April 2016 until August 2017. Although the Medical Center Chief of Logistics Service held his position from 2013 until January 2017,[105] after his departure the Medical Center relied on the emergency assistance of experienced CLOs from two other VA facilities to provide temporary leadership. After April 13, 2017, the Medical Center was reliant upon the temporary assistance of VISN 5 personnel until a CLO from another VA facility could be identified. In August 2017, the Medical Center hired a new Deputy CLO. A new Chief of Logistics Service also has been hired and entered his position on January 21, 2018.

SPS

The Medical Center and VISN received numerous reports documenting SPS understaffing resulting from hiring and retention deficiencies that included the following communications:

- The **November 2014** Logistics Study reflected that "[n]on-SPS staff attribute [instrument readiness and inventory] challenges to SPS understaffing," and "SPS is perceived as not equipped to meet current caseloads."
- A **September 2015** NPOSP report recommended that the Medical Center take action regarding a RME [Reusable Medical Equipment] Coordinator/Educator position as "[t]his SPS staff role is critical for the success of an SPS program in a [medical center] of this magnitude."
- An **October 2016** NPOSP report noted that SPS had a 45 percent vacancy rate (and that the Medical Center was using contract staff to fill three technician vacancies).
- An **April 2017** update from the Acting SPS Chief to Medical Center leaders noted that SPS was less than 50 percent staffed, with nine of 23 FTEs filled.[106]

The RME Committee minutes documented difficulties and delays in filling critical SPS positions between July 2015 and November 2016. Specifically, minutes reflected that the causes included

[105] At the Medical Center, the Chief of Logistics Service was the Chief Logistics Officer (CLO). In this report, the OIG uses these terms interchangeably.

[106] FTE refers to the equivalent of one full-time employee. One FTE can be filled by multiple part-time staff. (For example, two employees working 20 hours per week each would equal one full-time employee.)

deficient HR services, such as delays in the classification and posting of the SPS Chief, Assistant Chief, and RME Educator positions, and delays in hiring SPS technicians. Reflecting a lack of stable leadership, the OIG found that the duties of the SPS Chief, Assistant Chief, and RME Educator were being performed by a series of acting and detailed staff. From 2014 until July 2017, the Medical Center had two permanent and six detailed or Acting SPS Chiefs and the RME Educator duties were performed by a detailed Quality Management staff member.

In May 2017, the OIG found high vacancy rates persisted, although some progress had been made. The Medical Center reported that 17 of 23 FTEs were filled in SPS. As of July 2017, the Medical Center had brought on board a Chief and RME Educator for SPS. But, as of September 26, 2017, the Acting HR Director reported to the OIG that the SPS vacancy rate remained high (see Table 6).

Table 6. Vacancies in Logistics Service and SPS as of September 26, 2017

Service	Total Authorized Positions	Authorized Positions On Board	Percent of Total Authorized Positions Not On Board
Logistics	60	47	21%
Sterile Processing (SPS)	30	18	40%

Source: OIG analysis of Medical Center data provided by the Acting Medical Center HR Director in September 2017. The OIG was unable to independently validate the data due to inconsistencies in the Medical Center's documentation. On two occasions prior to September 26, 2017, the OIG received conflicting data regarding the number of vacant positions.

VHA leaders, including the Assistant Deputy Under Secretary for Health for Clinical Operations, stated that VHA has experienced difficulties in recruiting qualified SPS staff nationwide, in part because of a relatively low salary structure. This may have contributed to the Medical Center's persistent vacancies in SPS. However, if sufficient SPS staff were not available to meet clinical needs for reprocessing equipment, the Medical Center had other options including hiring additional contract or temporary staff, or curtailing services to ensure that staffing shortages did not compromise healthcare providers' ability to access needed instruments and equipment.

Lack of Adequate Staffing Plans

Inaccurate data concerning authorized positions across the Medical Center complicated efforts to develop appropriate staffing plans. In addition, a Resource Management Committee (RMC) that did not function as intended adversely impacted Medical Center leaders' decision-making and ability to fill these positions and staff services appropriately.

OIG staff interviewed the new Acting Medical Center Chief of HR in May 2017 to determine the current status of hiring actions and staffing. The Acting Chief reported a Medical Center-wide

35 percent vacancy rate. To validate this information and determine where key vacancies and gaps existed, the OIG requested a complete list of authorized positions. The Medical Center Fiscal Service was unable to provide the requested information because of inaccurate organizational charts.

The Medical Center Associate Director subsequently confirmed that the 35 percent vacancy rate reported to the OIG was inaccurate. In May 2017, there were 3,313 staff positions represented on the Medical Center organizational charts. In September 2017, the Medical Center determined that its actual authorized positions numbered 2,550, a difference of more than 700 positions. It reported a total of 292 "critical position" vacancies during FY 2017. As of September 6, 2017, 192 of those positions had been filled, with 101 of the 192 on board.

Resource Management Committee

The data inaccuracies may have existed in part because the RMC chaired by the Associate Director or Chief of Staff did not meet regularly. According to Medical Center policy, the RMC is responsible not only for recommending approval or disapproval of new positions and prioritizing hiring actions, but also for reviewing the business plans of services throughout the Medical Center.

The RMC actions are documented in committee minutes. The Medical Center RMC policy requires the Medical Center Director's signature on committee minutes, indicating approval of the committee's hiring recommendations before HR can proceed with the hiring actions.

HR staff who participated in and had knowledge of RMC processes told the OIG team that the committee is supposed to meet monthly as required by its charter. The committee failed to meet for an extended period of time prior to the end of 2016, which delayed the Medical Center's ability to authorize new positions as the need arose.

Deficiencies in HR

In addition to the difficulties described above, VHACO, VISN, and Medical Center leaders identified the following reasons for persistent staff vacancies and HR challenges across the Medical Center:

- The Acting Chief of Human Resources in April 2017 attributed persistent HR failures and staff vacancies to turnovers in HR leadership leading to a general lack of direction.
- The VISN Director cited the Medical Center's failure to implement recommendations related to staffing from VISN and VHACO site visit teams in late 2015 and throughout 2016, as well as high turnover rates in HR leadership.
- VHACO acknowledged national recruitment challenges in SPS.

The OIG confirmed that high turnover rates in HR leadership may have contributed to the failures of the Medical Center to resolve these issues. From January 2012 through July 2017, the Medical Center had 10 HR Chiefs (a combination of acting and permanent).

From September 2015 through October 2016, both VISN 5 and VHACO provided teams and personnel to support the Medical Center general HR functions. However, the Medical Center did not implement action plans developed from VISN and VHACO consultative site visits. Citing ongoing errors in hiring that continued within the Medical Center despite the assistance of VISN and VHACO personnel, the VISN 5 Director Joseph Williams concluded that the Medical Center "has been unable to sustain and maintain a sufficient HR program" and reassigned hiring functions to the VA Maryland Health Care System in February 2017. A memorandum of understanding (MOU) outlined the necessary steps to implement the arrangement that became effective in March 2017 for a period of 120 days. In June 2017, the agreement with VA Maryland Health Care System to assist with hiring and other human resources functions ended.

Actions Taken by the Medical Center to Fill Existing Vacancies

In its Interim Report, the OIG recommended that the USH expedite hiring of critical positions, such as the Associate Director, the Chief Nurse Executive, the Chief of Logistics, the Deputy Chief of Logistics, and supply technicians. As of September 6, 2017, a new Associate Director and Deputy Chief of Logistics had started work and a Chief Nurse Executive had been selected. Hiring actions for the Chief of Prosthetics and an Assistant Medical Center Director were still in progress as of December 2017. A new Chief of Logistics Service has recently been hired and entered his position on January 21, 2018.

As described above, the Acting Medical Center Director has also made substantial progress in addressing staff vacancies within Logistics Service. However, because of persistently high vacancy rates in SPS, and the other conditions described in this section and elsewhere in this report, the OIG makes the following recommendations.

Recommendations 19–20

Recommendation 19. The VISN 5 Director, together with Medical Center leaders, develops a staffing plan to fill vacancies that includes accurate numbers of authorized positions by service that is based on clinical and administrative workload and other appropriate measures, and includes contingencies for staffing areas with high attrition rates.

Recommendation 20. The VISN 5 Director ensures the timely completion of hiring actions at the Medical Center until staffing deficiencies in Logistics Service and Sterile Processing Services are fully resolved.

Results (Part III): Lack of Control Over Assets

The Medical Center lacked adequate financial controls, which contributed to a number of problems identified in this report. For example, failure to fully utilize a VHA-approved inventory system and multiple deficiencies in procurement compromised the ability of the Medical Center to meet supply needs using approved contracts and processes that assured accountability and oversight. In an effort to protect patients, some Medical Center personnel increasingly relied on government purchase cards to obtain necessary supplies and equipment.[107] The Medical Center's lack of controls over purchase card use, however, resulted in instances of employee misuse of purchase cards and generally increased the risk of fraud, waste, and abuse in the procurement of medical supplies.

In addition, while the Medical Center experienced shortages in some areas, stockpiles of medical supplies and equipment accumulated in an off-site warehouse. Staff were largely unaware of what was actually present in an unsecured off-site warehouse containing more than 500,000 items because of the Medical Center's inaccurate property inventory system. Some equipment in the warehouse sat for long periods of time, at risk of becoming obsolete, stolen, or damaged. The lack of internal controls at the Medical Center, lax access to the off-site warehouse, and ineffective procurement processes resulted in serious mismanagement of government assets and mishandling of patient protected health information (PHI) and personally identifiable information (PII).

This section of the report describes a number of deficiencies that put federal resources at risk for fraud, waste, and abuse:

- Inadequate oversight of purchase card use
- Failure to segregate personnel duties for purchasing from receiving or inventorying goods to ensure the integrity of procurement processes
- Failure to fully utilize a nonexpendable equipment inventory system
- Mismanagement of unused excess equipment
- Unsecured access to an off-site warehouse
- Unsecured access to PHI and PII

[107] FAR § 13.301 defines a government purchase card as a simplified acquisition method authorized for purchasing supplies, services, or construction. The purchase card is the preferred method for purchases under the micro-purchase threshold (currently $3,500); VA Financial Policy, Volume XVI, Chapter 1, *Government Purchase Card Program*, January 26, 2017, p. 3.

- Lack of adequate management controls over purchases related to supplies and equipment

Inadequate Oversight of Purchase Card Use

From October 1, 2014, through April 3, 2017, the Medical Center used purchase cards for supplies and equipment purchases totaling approximately $103 million. Of that purchase card amount, approximately $92 million (89 percent) was used for medical supplies and equipment, despite the availability of prime vendor contracts established for medical facilities nationwide. The Federal Acquisition Regulation encourages the use of agency contracts before considering open market vendors[108] in order to lower costs, promote standardization of agency purchases, and reduce the risk of unauthorized or unnecessary transactions. The OIG found that the heavy reliance on purchase cards grew in large part from the inventory issues discussed throughout this report.

Extensive Use of Purchase Cards by Employees Outside of Logistics Service

The Medical Center Logistics Service could not effectively identify low inventory levels and order proper quantities of medical supplies and equipment in a timely manner. As a result, the Medical Center CLO issued purchase cards to staff in order to quickly obtain medical supplies and equipment necessary for patient care. Across the Medical Center, a total of 283 purchase cards were issued to 151 unique purchase cardholders in various services throughout the hospital. Some personnel held more than one card.

According to the VISN 5 Purchase Card Program Manager, of the total 283 Medical Center purchase cards, the Medical Center CLO authorized 86 to be paid from a logistics fund control point (an account) for medical supplies. Only four of those 86 purchase cards, however, were assigned to Logistics Service staff. The remaining cards were issued to nonlogistics staff and purchases made with those cards could not be well tracked. According to the Acting and Deputy CLOs, the four cards assigned to Logistics Service staff were an insufficient number to purchase medical supplies.

VHA policy states that the VISN Director is responsible for ensuring that the purchase of clinical items using a purchase card is limited to staff in Logistics, Prosthetics Services, the Network Contracting Office, and Pharmacy.[109] Clinical staff are specifically prohibited from using purchase cards to order medical supplies.[110]

[108] FAR § 8.004.
[109] VHA Directive 1761.
[110] VHA Directive 1761, p. A-9.

Current VA policy states that an approving official will be responsible for not more than 25 purchase card accounts to ensure he or she can adequately review and verify the purchases monthly.[111] At the Medical Center, the CLO was responsible for approving expenditures made by all of the 86 cardholders. According to Medical Center staff, the Medical Center CLO approved the wider use of Logistics Service purchase cards (those tied to the logistics fund control point) to various Medical Center services as a work-around because Logistics Service could not always provide medical supplies when needed. Medical Center staff interviewed in July 2017 reported they did not trust Logistics Service to order necessary medical supplies in a timely and accurate manner.

Underutilized Prime Vendor Contracts

As noted, 89 percent of the Medical Center's use of purchase cards for supplies and equipment between October 1, 2014, through April 3, 2017, was for medical supplies and equipment despite the availability of prime vendor contracts established for medical facilities nationwide.[112] The OIG interviewed a Medical Center staff member who stated that personnel did not always use the medical-surgical prime vendor contract because Logistics Service staff had not added all of the items the Medical Center used to the formulary (the official list of medical supply items that can be ordered using the contract).

In May 2017, the Medical Center began tracking prime vendor contracts and determined that the Medical Center purchased six percent of needed medical supply items through the medical-surgical prime vendor contract, which was inconsistent with VHA policy goals. In June 2015, VHA established prime vendor purchasing goals and directed VISNs to buy all expendable clinical items through the contracts and to spend at least 40 percent of all medical/surgical funds using the contracts.[113] Despite this, many of the medical supply purchases were made from various vendors who were often local and could make same-day deliveries.

Previously identified problems from across multiple services contributed to these conditions. Because Logistics Service did not use a VHA-authorized inventory management system (GIP) to

[111] VA Financial Policy, Volume XVI, Chapter 1. This policy was in effect for a portion of the timeframe of the events discussed in this report. VHA Handbook 1730.01, *Use and Management of the Government Purchase Card Program*, September 2, 2008, which was in effect for the time frame prior to January 26, 2017, stated that the approving official was responsible for "monitoring no more than ten cardholders…to ensure they can adequately monitor every cardholder's purchases on a periodic basis." While the Facility Director could adjust the cardholders-to-approving-officials ratio on a case-by-case basis, the Handbook further stated "this ratio is never to exceed twenty cardholders to one approving official."

[112] A Prime Vendor Contract is one that provides commercial products at a contracted price to federal customers; such contracts generally grant customers a lower price because they buy a higher volume of products.

[113] Acting Deputy Under Secretary for Health for Operations and Management Memo to VISN Directors, Supply Chain Management Performance Improvement Through Increased Use of the Medical Surgical Prime Vendor Program, June 11, 2015.

track medical supply stock levels to maintain constant availability of expendable items, the Medical Center could not effectively identify low inventory levels and promptly order necessary quantities of medical supplies.

Lack of Appropriate Controls Over Purchase Card Use

Logistics Service did not effectively monitor purchase card use. This increased the risk of fraudulent purchases, as the following example illustrates:

- *In September 2016, the VISN 5 Agency/Organization Program Coordinator (A/OPC) for the purchase card program reported potentially fraudulent purchase orders to Medical Center leaders and the Chief of Prosthetics. According to the A/OPC, a purchasing agent falsely issued consults for several patients and used a purchase card to repeatedly buy cell phones and computers. From July until September 2016, the purchasing agent bought eight Microsoft Surface Pro computers, eight iPhones, and two iPads for the same veteran. After no action was taken by Medical Center leaders or the Chief of Prosthetics, the VISN 5 A/OPC reduced the available balance of the purchasing agent's purchase card to $1 and initiated an audit. The audit report concluded that the suspect purchases were fraudulent and the Medical Center Assistant Chief of Prosthetics recommended the purchase cardholder be terminated. In November 2016, the purchasing agent resigned.*

The excessive use of purchase cards also resulted in the increased potential for waste of taxpayer funds and creation of unauthorized commitments, as the following example illustrates.

- *In September 2017, National Contracting Office 5 (NCO 5) staff reported to the OIG that from October 1, 2014, to September 30, 2017, the Medical Center incurred $874,988.73 in rental fees for three specialized hospital beds assigned to specific patients for in-home use. In September 2017, the rental vendor provided the Medical Center with a proposal to purchase the equivalent beds (but brand new) for a total of $21,380.87 (plus $62,119.13 to satisfy the outstanding rental fees). Alternatively, the vendor gave the Medical Center the option to retain the three used beds in exchange for simply satisfying the outstanding balance of $62,119.13. NCO 5 staff told OIG inspectors that the rental beds were initially procured through the Medical Center Prosthetics Service using purchase cards and that the payments fell into arrears. Documentation shows that a past due balance began accruing in or about November 2015 and that the vendor had been making arrangements with the former Medical Center Chief of Prosthetics since at least December 2016 to resolve the unpaid invoices and to transfer the equipment ownership to the Medical Center. The Medical Center did not respond in a timely manner to the January 2017 proposal and an additional $20,929.57 in unnecessary rental fees accrued. As of*

September 2017, NCO 5 is working with the vendor to resolve the matter. If the Medical Center had better control and oversight over its purchase card use, it may not have incurred upwards of $875,000 in rental fees for three used beds.

The Medical Center CLO served as the final approving authority for Logistics Service purchases and was responsible for monitoring 86 purchase cards, which included ensuring purchases were legitimate expenditures.[114] Assigning approval responsibility for such a large number of purchase card accounts to one official created a backlog of pending purchase approvals and reconciliations that may have contributed to delays in filling orders and compromised the Medical Center's ability to quickly detect fraudulent purchases. For example, purchase card approvals exceeded 30 days in 13 percent of cases from FY 2015 through April 3, 2017. VA policy states cardholders and approving officials must reconcile all purchases at least monthly to ensure purchases were proper and payment prompt.[115]

VHA policy assigns the Medical Center Purchase Card Coordinator with responsibility for the overall purchase card program, which includes ensuring that medical supply purchases are limited to staff in Logistics Service, Prosthetics Service, and Pharmacy. However, when asked to identify unique purchase cardholders in each service who possessed a Logistics Services purchase card, the Medical Center Purchase Card Coordinator told OIG auditors that was "the Approving Official's responsibility." The lack of oversight of the purchase card program to make certain internal controls are followed exposed the Medical Center to the heightened risk of overpayment, fraudulent purchases, duplicate purchases, loss, and theft. During interviews, Medical Center staff reported two examples of medical supply item procurements using purchase cards in January 2017 that far exceeded the prime vendor prices:

- The Medical Center paid $289 per unit for specula on the open market that could have been purchased at $122.45 per unit from the prime vendor.
- The Medical Center was paying $899 per unit for butterfly needles on the open market that could have been purchased at $251 per unit from the prime vendor.

Documentation was insufficient for the OIG to determine whether a justification existed for purchasing items at a higher than otherwise necessary cost, such as an emergency. However, even if such a justification existed, VA policy requires the Medical Center to prioritize Federal Supply Schedule (FSS) sources over open market purchases.[116] With respect to the butterfly needles, documentation shows that two FSS vendors carried the same item priced at $172 and

[114] VA Financial Policy, Volume XVI, Chapter 1; VHA Handbook 1730.01.

[115] VA Financial Policy, Volume XVI Chapter 1. Previous guidance in the VHA Handbook 1730.01 was that" [a]ll payments must be reconciled or disputed within 40 calendar days."

[116] VA Acquisition Regulation 808.002, *Priorities of use of government supply sources.*

$158 per unit. By not obtaining medical supplies from the prime vendor, the Medical Center was not leveraging its purchasing power to obtain the items at reduced negotiated prices.

Until the Medical Center establishes a system of accountability, where the use of an inventory management system is enforced and purchase card usage is monitored, the Medical Center is at risk of fraud, waste, and abuse within its Purchase Card Program.

Recommendations 21–23

Recommendation 21. The Medical Center Director transitions purchase cards held by clinical staff and used for expendable medical supplies to Logistics Service staff, while ensuring that medical supplies can be obtained in a timely manner.

Recommendation 22. The Medical Center Director ensures that medical supply items are added to the prime vendor formulary in order to meet prime vendor purchasing goals.

Recommendation 23. The Medical Center Director makes certain that the Purchase Card Coordinator and approving officials monitor the issuance and future use of government purchase cards in accordance with VA Financial Policy.

Failure to Segregate Purchasing from Receiving Duties Increased the Risk for Fraud, Waste, and Abuse

Medical Center Logistics Service managers did not ensure segregation of duties for Logistics Service staff who were responsible for ordering medical supplies and equipment for the Medical Center from those who were responsible for receiving the items.

VA financial policies and procedures mandate segregation of duties. VA *Financial Policies and Procedures, 1358 Obligations*, outlines internal controls that require segregation of duties to make certain that individuals do not have authority for more than one of the following functions:

- Authorizing and approving the request for the obligation[117]
- Recording the obligation
- Certifying the receipt of goods or services and processing the payment

There was not segregation of duties for the ordering, payment, receipt, and distribution of expendable and nonexpendable items. The former Lead Inventory Manager expressed concerns that Logistics Service staffing was too low to properly segregate the duties. At the Medical Center, the former Lead Inventory Manager stated she was responsible for placing orders for medical supplies, making payments using a government purchase card, and accepting delivery of

[117] VA Financial Policy, Volume II, Chapter 6, *1358 Obligations*, January 2013 (modified in part 2017). "An obligation is a promise, commitment, or duty to make a future payment."

shipments. Once shipments were received, she would also retrieve the items and distribute them directly to the service areas. Because the same person was responsible for both placing orders, and then subsequently receiving and distributing them, the OIG confirmed the Medical Center did not maintain proper segregation of duties that would reduce the risk of fraud, waste, and abuse in the procurement of supplies and equipment.

Recommendation 24

Recommendation 24. The Medical Center Director maintains segregation of duties between personnel who order and purchase expendable and nonexpendable items and those who receive the items.

The Medical Center Failed to Appropriately Inventory Nonexpendable Equipment

Similar to the inventory discussion from Part II describing failures in the Medical Center's implementation of an effective system for inventorying *expendable supplies*, the Medical Center also failed to appropriately inventory *nonexpendable equipment*.[118] During a site visit in January 2017, VHA Procurement and Logistics Office staff stated that the Medical Center's "nonexpendable equipment program is practically nonexistent."

The failure to inventory nonexpendable equipment resulted in an inability to account for medical equipment and property used in the Medical Center, such as beds, refrigerators, and office furniture. In April 2017, the Medical Center CLO stated an inventory had not been conducted on nonexpendable property since FY 2015.[119] The lack of an inventory for nonexpendable equipment could have contributed to the accumulation of large amounts of property and equipment in an off-site warehouse.

VA Handbook 7002, *Logistics Management Procedures*, requires medical facilities to perform an annual physical inventory on all nonexpendable items and maintain an Equipment Inventory List (EIL). An EIL includes all nonexpendable property with assigned numbers that correspond to the responsible department. Although the EIL Custodial Officer is responsible for completing and signing the EIL, the Medical Center Director and CLO (or their designee) must ensure accountability and oversight for all nonexpendable property and equipment in their facility. The Medical Center CLO failed to submit data for the VHA Quarterly EIL reports for three years. These quarterly reports inform VHA Procurement and Logistics Office of Medical Center EIL completion.

[118] Expendable supplies are disposable items typically used one time. Nonexpendable equipment has a continuing use, is not consumed in use, and has an expected service life of two or more years.

[119] At the time of this interview, the 2017 inventory was in process but had not been completed.

As mentioned in the OIG Interim Report, documentation showed 27,494 items valued at more than $154,876,092 were unaccounted for during the previous 12 months and should have been reported on an EIL. A March 21, 2017 memorandum sent from the DUSHOM Steve Young to VISN 5 Director Joseph Williams and Medical Center Director Brian Hawkins stated that Reports of Survey listing lost or stolen property had not been completed in more than five years.[120] Without conducting required inventory assessments and Reports of Survey, the Medical Center could not determine the quantity of items on hand or ensure the risk of equipment loss or theft was minimized.

- *During a site visit to the Medical Center off-site warehouse in April 2017, OIG staff observed several boxes containing what appeared to be new refrigerators. These purchases were authorized in September 2011 for a total of $79,991. Due to the lack of accompanying documentation and the absence of barcodes, the OIG could not determine why these items had been stored in the warehouse. Medical Center staff said the refrigerators might have been stored in the warehouse because they were not holding the temperature required for medication storage as intended. No documentation was found to support these claims.*

In FYs 2013, 2015, and 2017, an outside vendor was contracted to conduct a wall-to-wall inventory of nonexpendable items. The vendor Project Lead stated the company provided data to the Medical Center CLO at the end of each inventory. The vendor Project Lead explained that his/her team marked equipment as the items were inventoried and the Medical Center Logistics Service staff were expected to review the items and create barcodes. Barcodes are used to track items in VA's equipment tracking system, the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS). OIG staff found the vendor's labels from previous inventories on equipment that did not have Medical Center barcodes. The Medical Center Logistics Service failed to place barcodes on these items to track them in an inventory system.

In early April 2017, the Acting Medical Center CLO confirmed that Medical Center staff were purchasing nonexpendable equipment items but not entering the information into AEMS/MERS. A former Medical Center CLO also stated that a process for reviewing nonexpendable equipment purchases to determine if the items were put to use was not in place. Without these reviews, the Medical Center could not fully account for expenditures.

The Medical Center plans to implement an asset tracking system, the Real Time Location System (RTLS), in 2018. The RTLS asset-tracking option will interface with AEMS/MERS to provide the location of the equipment item as well as the status, environmental conditions, usage,

[120] VA uses a "Report of Survey" system to obtain explanations of circumstances surrounding government property loss, damage, or destruction occurring because of something other than normal wear and tear.

and specific movement of the item. Because the system interfaces with AEMS/MERS, Medical Center Logistics Service staff will be able to update and ensure the accuracy of the reported information.

Recommendations 25–26

Recommendation 25. The VISN 5 Director ensures that the Medical Center updates and maintains the Equipment Inventory List (EIL) as required by VA policy and makes certain that the Medical Center Director and Chief Logistics Officer are held accountable for the timely and accurate reporting of the Medical Center EIL.

Recommendation 26. The Medical Center Director ensures that equipment is accurately and timely entered into the Automated Engineering Management System/Medical Equipment Reporting System.

Unused and Excess Items Accumulated and Were Not Properly Managed

The Medical Center Logistics Service failed to ensure that staff appropriately accounted for excess items by using either the VA 2237 Request Form, *Turn-In and Receipt for Property or Services* or AEMS/MERS for proper disposition as required by VA Handbook 7348, *Utilization and Disposal of Personal Property*. Expendable or nonexpendable property is considered "unrequired" if the requesting service no longer needs the property or the property becomes unserviceable through normal use.[121] VA Handbook 7348 further requires that medical facilities report excess property to the U.S. General Services Administration (GSA) and that they try to obtain excess items from other agencies to fulfill their own needs.[122]

An employee detailed to the Medical Center observed staff taking items to the Medical Center off-site warehouse for storage without completing the required VA Form 2237. VISN and Medical Center staff also reported that the off-site warehouse was used as a dumping ground for the Medical Center. Medical Center Logistics Service managers reported that their staff did not

[121] VA Handbook 7002, part 4, 15.a.

[122] VA Handbook 7348, *Utilization and Disposal of Personal Property*, March 30, 2012. "In order to be good stewards of federal government funds, each VA facility is obligated to use all of its property until no longer functional or required. When a facility deems an item as no longer needed, it does not necessarily mean the same item could not be utilized elsewhere within the same facility. A mechanism will be established to ensure unrequired property is made available and publicized internally at each VA facility in order to maximize utilization."

have access to the GSA website in order to sell unrequired items.[123] OIG staff observed items such as the following stored in the warehouse:

- Cardboard boxes
- IT equipment
- Ceiling tiles
- Refrigerators
- Lighting
- Office equipment
- Office paper (one-year supply)
- Burial flags
- Massage chairs
- Cases of five-gallon water jugs
- Hospital beds
- Dental equipment
- Generators

Failure to fully utilize an inventory system meant that Medical Center staff did not know what was in the warehouse and could not, therefore, make use of its contents.

OIG team observations and statements from VISN and Medical Center staff revealed that when items were purchased and deemed unusable or ordered in error, the item was not returned but rather taken to this off-site warehouse without further action or accountability. For example,

- *A VHA employee stated that approximately 185 beds were ordered, but upon receipt the requesting service staff determined they were not suitable for their needs. The beds were taken to the off-site warehouse and stored without further disposition.*
- *OIG staff observed two forklifts in the off-site warehouse, which the Medical Center authorized for purchase in September 2012 for approximately $44,000 and received in February 2013. A VHA staff member stated the forklifts were purchased for use at the on-site warehouse, but upon receipt, the forklifts were too large for the warehouse and could not be used. The items were then moved to the off-site warehouse. As of April 2017, they remained in the warehouse.*

Medical Center Logistics Service staff also stored noninventoried medical supplies in an on-site warehouse. Obsolete and excess medical supplies were stored in this location within the Medical Center with no accountability.

- *The OIG identified about 420 cases containing 8,400 blood pressure cuffs, valued at approximately $24,746, located in the on-site warehouse. The cuffs were ordered by the former Medical Center Inventory Management Supervisor as part of an FY 2016 year-end purchase. The Medical Center Inventory Management Supervisor*

[123] GSA maintains a website used to sell surplus real and personal property owned by the federal government to other federal, state, and local agencies, as well as to private U.S. citizens. See https://www.gsa.gov/acquisition/government-property-for-sale-or-disposal.

confirmed the blood pressure cuffs were excess items and labeled for return; however the supervisor did not perform the steps required to make the blood pressure cuffs available to other medical facilities.

Warehouse Areas Were Unsecured

The former Medical Center CLO failed to control who could access items stored in both the on-site and off-site warehouses. The OIG team observed Medical Center staff walking freely in and out of the on-site warehouse. The former Medical Center Assistant Warehouse Chief stated that several warehouse staff had keys and access to the off-site warehouse but could not provide an exact number of personnel who were authorized access. Some of the equipment in the warehouse was visibly dirty or appeared to be broken, while other items were unused and in unopened boxes. An unsecure warehouse makes it easier for personnel to dump unwanted items without accountability, as well as subjecting items to theft or damage.

The OIG team found a storage container at the Medical Center that was unlocked and contained several medical equipment items, such as five dental chairs. The Medical Center Chief of Facilities Management Service stated he was unaware the container had medical equipment stored inside and acknowledged the container was unlocked. Because the container was not secured, unauthorized individuals had easy access to this government property.

Figure 3. Hospital Beds and Equipment at Off-Site Warehouse

Source: VA OIG photo; Washington DC VAMC off-site warehouse; 1:38 p.m., April 5, 2017

Following the Interim Report, the OIG secured the contents of this warehouse and contracted for an independent inventory of its contents as part of an investigation concerning potential criminal activity. This inventory determined that the off-site warehouse contained 588,152 items. OIG criminal investigators continue to conduct a review of the inventory results and VA procurement records in an attempt to place a monetary value on the contents of the warehouse.

The OIG released the contents of the warehouse to the Medical Center on August 1, 2017, for proper disposition. As of September 19, 2017, the Medical Center had not taken further steps. The Deputy CLO, who started in his position in August 2017, stated that he was unaware that the

contents of the warehouse had been released for disposition until September 19. The Medical Center has extended an agreement with the owners of the off-site warehouse to permit the continued use of the warehouse through April 30, 2018.

Recommendations 27–28

Recommendation 27. The Medical Center Director ensures that unrequired equipment is turned in for disposition consistent with VHA policies and procedures.[124]

Recommendation 28. The Medical Center Director properly secures all areas used to store medical equipment and supplies.[125]

Failure to Secure Storage Areas Also Permitted Mishandling of Patient Protected Health and Personally Identifiable Information

Medical Center staff did not consistently and appropriately secure patient PHI and PII as required by policy.[126] OIG staff found documents containing PHI and PII at the off-site warehouse in a large trash dumpster on April 12, 2017, and outside the main Medical Center on April 13 in two lockable metal intermodal containers, one of which did not have a lock.[127]

During the course of the OIG inspection and as late as May 9, 2017, unsecured and improperly stored boxes containing PHI and PII were found in various locations including the off-site warehouse, on-site warehouse, basement, and other areas in the Medical Center. The OIG took possession of the unsecured loose documents and 1,307 boxes of documents and placed them in secure locations within the on-site storage areas and the main hospital basement. Only authorized individuals have controlled access to these areas. Because these unsecured and improperly dispositioned documents could have been accessed by unauthorized individuals, confidential patient information was at risk for identity theft or other misuse.

[124] This recommendation is consistent with the Interim Report recommendation that "[t]he Under Secretary for Health takes all appropriate steps to ensure that the Washington DC VA Medical Center and Veterans Integrated Service Network arrange for the orderly movement of goods and supplies from the warehouse that minimizes losses to the Government."

[125] This recommendation also builds on the Interim Report recommendation that "[t]he Under Secretary for Health take immediate action to create an inventory and establish accountability over the equipment and supplies in the off-site warehouse."

[126] VHA Handbook 1605.2, *Minimum Necessary Standard for Protected Health Information*, January 23, 2013.

[127] Metal intermodal containers have a double door on the end for access to the container and are used to store and transport contents between locations.

Failure to Assign Responsibilities for Records Management

The Medical Center Director is responsible for ensuring that all requirements are met for the creation, maintenance, use, storage, and disposition of records, including that the storage locations meet National Archives and Records Administration (NARA) criteria.[128] VHA policy mandates that the Medical Center Director assign an official records manager, an alternate records manager, and official records liaisons for each section within the facility.

Medical Center records were not properly stored, maintained and disposed of in part because the Medical Center Director failed to assign a records manager in accordance with VHA policy. The OIG determined that there was no assigned records manager since at least 2013, nor had the Medical Center Director consistently assigned official records liaisons.[129]

The records manager position is, according to VHA policy, responsible for a number of vital functions related to the proper storage and management at the facility level, including

- Developing and disseminating policies and procedures related to records management;
- Maintaining a facility-wide records inventory;
- Coordinating records storage and disposition within VA records storage facilities;
- Ensuring all records liaisons are trained on the creation, maintenance, use, storage, and disposition of the records created within their area of responsibility;
- Maintaining and destroying federal records in the facility within the specified time frames defined in VA policy; and
- Resolving records management issues that arise at the facility.[130]

Liaisons are individuals who have assigned responsibility for ensuring that records are stored, maintained, and disposed of properly within their departments.

Because the Medical Center did not have anyone formally designated to perform the duties of the records manager or records liaisons, documents with PHI and PII were not consistently secured and dispositioned as required. These lapses placed patient data at risk for intentional or inadvertent disclosure.

[128] VHA Directive 6300, *Records Management*, July 10, 2012.
[129] VHA Directive 6300.
[130] VHA Directive 6300, p. 4.

Follow-Up and Corrective Actions

Although the documents in the dumpster and two intermodal containers were at the most risk for improper use or disclosure, the documents in the unsecured boxes found in the Medical Center sub-basement could also compromise patient privacy and confidentiality. OIG investigators reviewed the contents of each of the 1,307 boxes that were discovered during the course of the investigation. Of this total, 1,058 (81 percent) contained PHI and PII, including individual patient pulmonary function studies, veterans' identification cards, patient health records and films, as well as personnel and other administrative documents. The dates of the records spanned from the 1970s to 2015.

The Acting Medical Center Records Manager communicated with the VHACO Privacy Officer as well as staff from the VHA Records Management Office to develop an action plan for notification of patients, as appropriate, and to determine further actions needed for disposition of all the documents.

Recommendations 29–30

Recommendation 29. The Medical Center Director designates an official records manager, alternate records manager, and official records liaisons, as well as implements a records management program in accordance with the National Archives and Records Administration requirements.

Recommendation 30. The Medical Center Director verifies that actions have been taken to notify patients when their information may have been improperly accessed, as appropriate.

The Medical Center Lacked Effective Internal Controls for Purchases

The Medical Center accumulated an extensive surplus of medical supplies and equipment, in part, because Fiscal Service lacked effective internal controls for purchases. These controls would have identified the amount the Medical Center spent on its medical supplies and equipment and helped determine if the purchases were consistent with patient demand at the proper quantity and lowest price. The lack of effective internal controls also resulted in practices that undermined the Medical Center staff's ability to track expenditures to the item level, ensure the integrity of purchasing processes, and provide accurate medical supply and equipment expenditure data to VISN 5 and VHA leaders.

Government Accountability Office (GAO) standards require that management clearly documents internal controls over all transactions and other significant events in a manner that allows the documentation to be readily available for examination.[131] Further, GAO standards require

[131] Government Accountability Office, *Standards for Internal Control in the Federal Government*, September 2014.

documentation and records to be properly managed and maintained. However, according to a former CLO, the Medical Center could not always accurately identify the specific medical supply and equipment items purchased due to the lack of source documents such as purchase orders, invoices, and medical supply and equipment receiving reports needed to specifically identify purchases to the item level. This also resulted in an inadequate audit trail for the OIG to independently verify the reasonableness of Medical Center medical supply and equipment purchases.

The inability to track purchases and ensure the integrity of the process was due, in part, to the Medical Center deficiencies described in other sections of this report—failures to consistently and effectively use VHA-authorized inventory management systems, such as GIP and AEMS/MERS; the failure to segregate personnel duties for ordering and receiving medical supply and equipment items; and inadequate controls over government purchase card use. Taken together, there is no assurance that necessary medical supply and equipment items have been properly purchased and appropriate quantities stocked in the Medical Center for patient care. In addition, the lack of documentation and internal controls related to medical supply and equipment purchases increased the Medical Center's risk for unauthorized or unnecessary purchasing, overspending, and for items being stolen or diverted for personal gain.

Medical Center Funding for Medical Purchases

A number of Medical Center staff reported that they were told by Medical Center Logistics Service staff and managers that supply shortages were due to insufficient funds for medical supplies and equipment. However, a review of the Medical Center overall budget revealed that from October 2014 to October 2017, the Medical Center received its allocated funds. An assessment of funding was not conducted, however, to determine whether the allocations received were sufficient to meet the medical supply and equipment demands.

The Medical Center provided OIG staff with its total general and specific purpose allocations, corresponding obligations, and expenditures for FYs 2015–2017. The OIG compared allocated amounts to the obligated and expended amounts to determine how close the Medical Center was to spending its allocated funding (see Table 7).

Table 7. Medical Center Allocated, Obligated, and Expended Amounts
FYs 2015–2017 (in millions, except where stated)

FY	End-of-Year Allocations	Obligations	Expenditures	Remaining Allocation
2015	$565	$560	$495	$5
2016	$488	$485	$477	$3
2017	$562	$546	$507	$16
Totals	**$1.6B**	**$1.6B**	**$1.5B**	**$24M**

Source: Medical Center staff provided data from the Financial Reporting System (FRS). FY 2017 figures are through October 31, 2017. Of the $16 million that remained available for allocation in FY 2017, $10.1 million is carryover for FY 2018 Hepatitis C medication costs. The Remaining Allocation column = End-of-Year Allocations minus Obligation.

During FYs 2015–2017, according to the Medical Center, its end-of-year allocation (all allocations received during that fiscal year) exceeded $480 million for each year. The OIG determined that the Medical Center and VISN 5 did not conduct an analysis to determine whether these funds were adequate and exercised few controls over how the Medical Center spent these funds.

The OIG reviewed the expenditure data provided by the Medical Center to determine how much was reported as spent to purchase medical supplies and equipment (see Table 8).

Table 8. Medical Center Medical Supply and Equipment Expenditures
FYs 2015–2017 (in millions)

FY	Medical Supply Expenditures	Medical Equipment Expenditures	FY Totals
2015	$95	$5	$100
2016	$85	$6	$91
2017	$80	$3	$83
Totals	**$260**	**$14**	**$274**

Source: Medical Center staff provided data from the FRS. FY 2017 figures are through September 13, 2017.

The OIG determined that any perceived lack of funding for medical supplies was most likely due to the absence of effective internal controls over purchases and inventory, which precluded the Medical Center from knowing what items were being purchased by the various services and whether the items were obtained at the proper quantity and cost.

Despite the size of the annual end-of-year allocations for the Medical Center budget, the OIG was unable to obtain reliable expenditure data and other critical information from VISN 5 or the Medical Center that would have indicated the adequacy of funding for overall operations or for medical supply and equipment purchases specifically. Relying solely on funding allocation

models does not adequately provide assurance that a medical facility's funding is sufficient and that resources were properly directed where they were needed.

Medical Center Inability to Account for Purchases

The Medical Center Fiscal Service lack of internal controls over medical supply and equipment purchases, including the lack of supporting documentation, did not allow the OIG to determine if purchases were justified. According to accounting records provided by the Medical Center, of the approximately $1.6 billion in Medical Center obligations from FYs 2015–2017 (through September 2017), about $274 million was spent on the purchase of medical supplies and equipment. The VISN 5 CFO provided the Medical Center operating plan for the same time period that identified an estimated $217 million would be spent on medical supply and equipment purchases.

Multiple Medical Center staff stated that medical supply and equipment items were not tracked upon receipt. According to a former Acting Chief of Logistics, staff receiving orders did not routinely collect and analyze supporting documentation such as purchase orders, receiving reports, and invoices to ensure they obtained the correct quantity at the right price. The OIG attempted to trace selected FY 2016 medical and prosthetic supply transactions to the item level. Indicative of the magnitude of the problems inherited by the Acting Medical Center management, underscoring the impact of persistently unstable leadership, and illustrative of how difficult it was to gather necessary audit information, various acting Medical Center managers in key positions could not locate all of the necessary corresponding documentation to support the selected purchases:

- The Acting Chief of Prosthetics stated in May 2017, *"We are unable to provide descriptions for the purchases as they are imbedded in patient consults and the quantity requested would be numbering around approximately 500,000."*
- The Acting Chief Logistics Officer stated, *"I have looked at some of these…I do not have any detailed documentation for these transactions."*
- The Acting Deputy Chief Logistics Officer stated, *"I have been detailed here since April 14 and as near as I can tell no transaction records of any kind were kept by the previous leadership team."*
- The Acting Assistant Medical Center Director stated, *"These look like they may be logistics obligations. I will meet with the Acting Chief of Prosthetics and fiscal to see if we can track down who submitted the requests, [so] the documentation can be uploaded."*

Due to the lack of adequate and complete source documentation, the OIG was unable to specifically determine all of the medical supply and equipment items purchased by the Medical

Center. Moreover, the lack of evidence to support an audit trail increases the risk for potential fraud, waste, and abuse of Medical Center medical equipment and supplies.

Lack of Controls for Oversight of Medical Center Supply and Equipment Purchases

Then Medical Center Director Brian Hawkins, the former CLO, and the CFO signed the Annual Certification of Accounting Records (2014–2016) indicating that the Medical Center's internal controls were working as intended to mitigate risks. The OIG found a pervasive lack of accountability at all levels of VHA management for the oversight of Medical Center medical supply and equipment purchases beyond requiring this certification.[132] According to one VHACO official, no one independently validated the Medical Center self-certification of its accounting records. As such, there is no reasonable assurance that internal controls had been established and were working to mitigate risks.

VA financial policy states the VHA CFO and subordinate CFOs (including the Medical Center CFO) perform internal control activities to mitigate the risks of misstating, misrepresenting, or losing information (to include supporting documentation) for its expenditures.[133]

When assessing the extent to which internal controls were implemented, the OIG asked VHA managers who should provide oversight over medical supply and equipment purchases at the Medical Center. The OIG found a circular pattern of shifting responsibility and assigning blame between VHA program offices, VISN 5, and the Medical Center. VHACO officials shifted responsibility to VISN 5. The VISN 5 officials shifted responsibility to the Medical Center. The Medical Center Director shifted responsibility to Logistics Service. The Logistics Service staff assigned blame to the lack of oversight by the VHA program offices, VISN 5, and Medical Center leaders. No single management official from the various offices or departments reviewed ultimately took responsibility for oversight of the Medical Center medical supply and equipment purchases.

This failure at multiple managerial and administrative levels to acknowledge responsibility and exercise proper internal controls contributed to the breakdown of the Medical Center medical supply and equipment purchasing and inventory management processes. As a result, individuals and departments within the Medical Center took on the responsibility for addressing their own medical supply and equipment purchase needs without the benefit of proper internal controls to help make certain orders were at the proper quantity and at the best price.

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[132] VA Financial Policy, Volume VII, Chapter 2, *Consolidated Financial Statements*, September 2017. The Annual Certification of Accounting Records is the Medical Facility's Management assertions that its internal controls provide reasonable assurance that programs are working as intended to mitigate risks.

[133] VA Financial Policy, Volume I, Chapter 1B, *Quality Financial Information Volume 1*, December 2010 (updated February 22, 2018).

Recommendations 31–32

Recommendation 31. The Medical Center Director verifies that accurate and complete financial documentation to support medical supply and equipment purchases is readily available in accordance with GAO *Standards for Internal Control in the Federal Government*.

Recommendation 32. The VISN 5 Director audits a representative sample of FY 2017 Medical Center supply, instrument, and equipment purchases and ensures adequate internal controls for future purchases are in place.

Results (Part IV): Failures in Leadership

Medical Center, VISN 5, and some VHACO leaders have known for years about at least some of the problems outlined in this report. Yet at multiple levels of leadership, there were failures in accountability, responsibility, and oversight. This lack of ownership and a pervasive practice of shifting blame to others contributed to a culture of complacency and neglect that placed both patients and assets of the federal government at risk. The Medical Center, VISN 5, and VHACO collectively generated and received many reports between 2013 and 2017 that identified supply, inventory, and equipment issues at the Medical Center. Despite an exhaustive list of recurring recommendations, leaders within VA at every level failed to correct those conditions and their underlying causes. Some leaders cited the absence of patient deaths or injuries as a justification for the lack of urgency in resolving identified problems. They also reported not being aware of the scope of the deficiencies and ongoing bureaucratic and staffing challenges that undermined efforts. Although some progress has been made since the issuance of the Interim Report, the OIG has identified weaknesses in oversight that must be corrected going forward.

The OIG determined that the Medical Center Director, VISN 5 leaders, and some VHACO personnel received reports about supply, instrument, and equipment issues at the Medical Center for years prior to the issuance of the OIG Interim Report and did not take effective corrective actions.

This section provides the following:

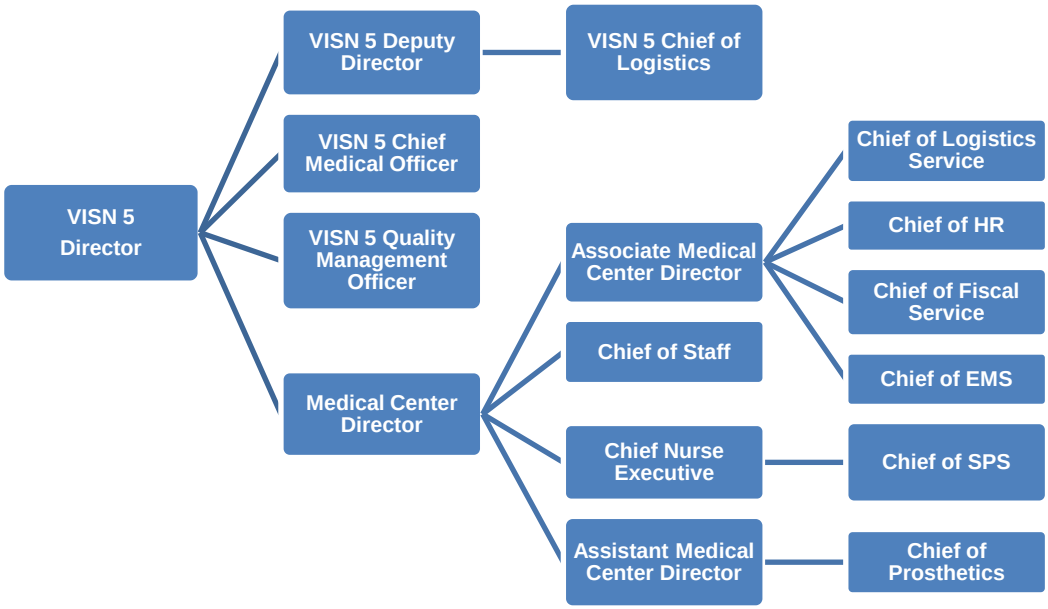
- An overview of Medical Center and VISN 5 leadership structures
- A review of prior reports about a range of persistent deficiencies in the Medical Center
- Failures by the Medical Center Director and Associate Medical Center Director to address identified problems
- Concerns regarding ineffectual VISN 5 oversight
- Concerns regarding VHACO oversight, including a discussion of the analysis of available data, the failed Catamaran migration, the VHA star rating system and the Medical Center 3-star (average rating) status

Medical Center and VISN 5 Leaders Were in Positions to Effect Change[134]

Brian A. Hawkins became Medical Center Director in 2011 and served in this capacity until April 2017. As Medical Center Director, Mr. Hawkins had overall responsibility for oversight of all aspects of medical, administrative, and support operations for the facility.

Mr. Hawkins reported directly to the VISN 5 Director, a position that was held by Fernando O. Rivera from December 2010 to December 2014 and by Joseph A. Williams, Jr. from January 2015 to this writing. Mr. Williams served in an acting capacity until approximately April 2016 when he was appointed permanently. As VISN Directors, Mr. Williams and Mr. Rivera oversaw the delivery of health care and the operating budget of the VISN's several medical centers and clinics (VISN facilities).

Figure 4. Medical Center and VISN 5 Leaders Responsible for Addressing Medical Center Deficiencies (January 2013–March 2017)



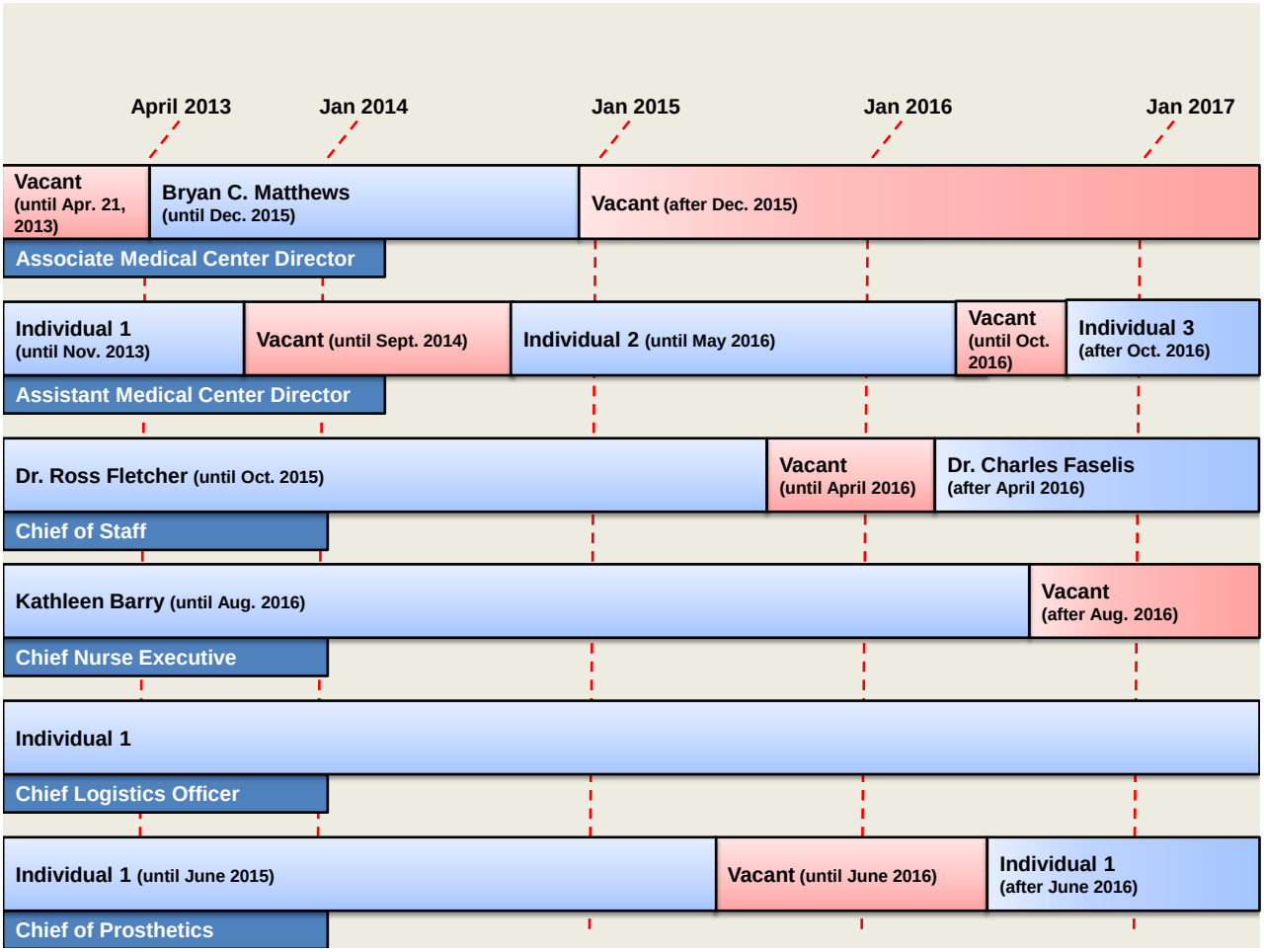
Source: OIG analysis of Medical Center and VISN 5 Organizational Charts 2013–2017[135]

[134] For this report, OIG has not listed the names of VA and VHA leaders who held positions below the GS-15 level (or its equivalent).

[135] Functional Organization Manuals, 2013, 2014, 2015, 2016, 2017.

Relevant Medical Center senior leaders who reported directly to Mr. Hawkins from January 2013 to March 2017 are outlined in Figure 5.

Figure 5. Relevant Medical Center Senior Leaders Reporting to the Medical Center Director (January 2013–March 2017)



Source: OIG analysis. "Vacant" reflects periods of time when the position did not have a permanent incumbent. During these periods, other personnel may have been temporarily appointed to serve in an acting capacity. To the extent that such temporary appointments are relevant to the report, they are addressed in the narrative. "Individual" represents a staff person who held the position below the GS-15 level (or its equivalent).

As Associate Director until December 2015, Mr. Matthews was responsible for leading Medical Center administrative services and operations including Logistics Service, HR, Fiscal Service, and EMS.

As Chiefs of Staff, Drs. Fletcher and Faselis were responsible for the efficient operation of Medical Center clinical functions, which included oversight of staff, facilities, equipment, and supplies needed to implement an integrated program that meets patient care needs. Multiple interviewees credited Dr. Faselis with Medical Center improvements in clinical performance

measures (Strategic Analytics for Improvement and Learning (SAIL) measures) in FY 2016. As Chief Nurse Executive (Chief Nurse), Ms. Barry was responsible for Nursing and SPS until her departure in August 2016.

VISN 5 senior leaders who reported directly to Mr. Rivera or Mr. Williams from January 2013 to March 2017 are outlined in Table 9.

Table 9: Relevant VISN 5 Senior Leaders Reporting to the VISN Director
(January 2013–March 2017)

Position	Name
Deputy Director	Guy Richardson
Chief Medical Officer	Dr. Raymond Chung

Source: OIG analysis

As VISN 5 Deputy Director, Mr. Richardson had oversight responsibilities for administrative operations throughout the VISN, including Logistics Service. In his position as VISN 5 Chief Medical Officer, Dr. Chung was charged with overseeing clinical functions.

VISN 5 management also included a CLO who reported to Mr. Richardson and was responsible for program and policy oversight of Logistics Services for all VISN facilities. The CLO position was vacant from March 2015 to approximately May 2016.

Many Previously Reported Deficiencies Persisted Despite Leaders' Being Put on Notice

From 2013 to 2016, the Medical Center and VISN 5 received at least seven written reports detailing significant deficiencies in the Medical Center Logistics, Sterile Processing, and Nursing Services—many of which the OIG team found persisted during multiple 2017 site visits.

(1) 2013 Management Quality Assurance Logistics Business Review Identified Significant Deficiencies in the Medical Center Logistics Service

The VA Management Quality Assurance Service (MQAS) reviewed the Medical Center "to evaluate the performance of selected areas of logistics operations and identify areas requiring improvement."[136] MQAS provided a written report of its findings and recommendations to Mr. Hawkins on January 18, 2013. The MQAS report was simultaneously provided to the VHA

[136] MQAS was a suborganization of VA and did not report to the Under Secretary for Health. MQAS conducted advisory reviews to evaluate VA compliance with various federal laws and regulations. As of February 2018, VA implemented organizational changes transferring this compliance review to the VHA Office of Procurement and Logistics.

Procurement and Logistics Office, and VISN 5 leaders including Mr. Rivera. The MQAS report "identified 52 conditions, including 9 repeat findings, and 2 concerns related to compliance with VA and VHA directives that require[d] management attention." Mr. Hawkins, Mr. Matthews, and the Medical Center CLO bore responsibility for addressing the issues raised by the MQAS report. Mr. Matthews became Associate Medical Center Director approximately two-and-a-half months after the MQAS report was published. He received a copy of the MQAS report and participated in follow-up correspondence tracking Medical Center progress in meeting action items identified by the report. When OIG staff interviewed him in 2017, he stated that he had no recall of the MQAS report or its recommendations.

The MQAS report contained adverse findings relating to Medical Center nonexpendable property management, expendable supply management, sterile storage, and other related operations. The MQAS report indicated that the Medical Center was not using GIP to maintain its inventories as required by VHA directives. The nonuse of GIP was reported as a "significant regression" from the conditions found at the Medical Center when MQAS evaluated it in 2007. With respect to expendable supply management, the MQAS report concluded that the deficiencies "occurred because [the VISN 5 CLO, the Medical Center CLO, and Medical Center Logistics Service] staff did not adhere to the directives and mandates necessary to fully implement and maintain proper inventory processes, procedures, and VHA reporting requirements."

MQAS requested a response by March 1, 2013, detailing Mr. Hawkins' concurrence with the recommendations and identifying planned corrective actions and implementation dates. MQAS exchanged an agreed-upon action plan with the Medical Center in March 2013, and by May 2013 the Medical Center provided representations that it had addressed eight of the 52 recommendations. However, on December 18, 2013, an MQAS representative emailed the Medical Center CLO and others writing, "I haven't heard or received any responses from your office since August 20, 2013. Your estimated completion date[s] are past due. We have tried numerous times to contact you and your office to support the implementation of agreed corrective actions."

In February 2014, more than a year after issuing the report, an MQAS representative wrote to Mr. Hawkins, copying Mr. Rivera and other VISN 5 personnel, stating, "Our records indicate your [Medical Center] is delinquent in taking recommended logistics business operations corrective actions." The Medical Center responsiveness did not improve.

A Deputy Under Secretary for Health for Operations and Management (DUSHOM) March 11, 2009, Memorandum outlined the following duty for the VHA Procurement and Logistics Office for implementing logistics-related MQAS findings:

> *"[The Procurement and Logistics Office] will review [facility] responses and provide them to MQAS and/or return to the facilities if it is determined that additional information or action is required.*

> *Additionally, [the Procurement and Logistics Office] will be responsible for validation of action indicated by the facilities as well as monitoring and reporting to this office and MQAS on completion of action."*[137]

In June 2014, MQAS sought the assistance of the VHA Procurement and Logistics Office regarding the Medical Center lack of response. VHACO Director of Logistics Operations and the Lead Program Manager for Logistics Operations contacted the VISN 5 CLO to request an update and offer assistance if the Medical Center was "struggling with something in particular." In a July 2014 correspondence, the VISN 5 CLO admitted that the VISN "may have dropped the ball on response."

In October 2014, MQAS wrote to the VISN 5 CLO, "We are still not receiving any responses from Washington D.C. VAMC (688).[138] We soon will have to elevate this review if [the Medical Center CLO] does not become more responsive to our requests." The Medical Center resumed responding in piecemeal fashion to implement the agreed-upon action items. By December 2015, based upon the representations of the Medical Center CLO and his staff, MQAS determined that the Medical Center had satisfied all but one of the MQAS recommendations. MQAS held open the recommendation that required the Medical Center to "ensure expendable supplies in all established [primary inventory locations] are appropriately managed and that long supply is reduced to less than 10 percent of the total inventory value."[139]

The agreed-upon action plan required the Medical Center to demonstrate its compliance by providing MQAS with a "stock status report" showing that long supply had been reduced to the specified level. An accurate report could only be generated if the Medical Center had implemented and maintained GIP for a duration sufficient to build supply usage data over a period of months. However, the Medical Center never fully implemented GIP and was not able

[137] Deputy Under Secretary for Health for Operations and Management. *Management Quality Assurance Service (MQAS) Logistics Business Review Reports* (WebCIMS No. 421978), March 11, 2009.

[138] The 688 designation is the Medical Center's code number.

[139] "Long supply" refers to expendable supplies held in inventory that exceed what is actually required to be held for a given period of time.

to generate the requested report.[140] MQAS continued to follow up with Medical Center Logistics Service staff in February 2017, but had not received the required report.

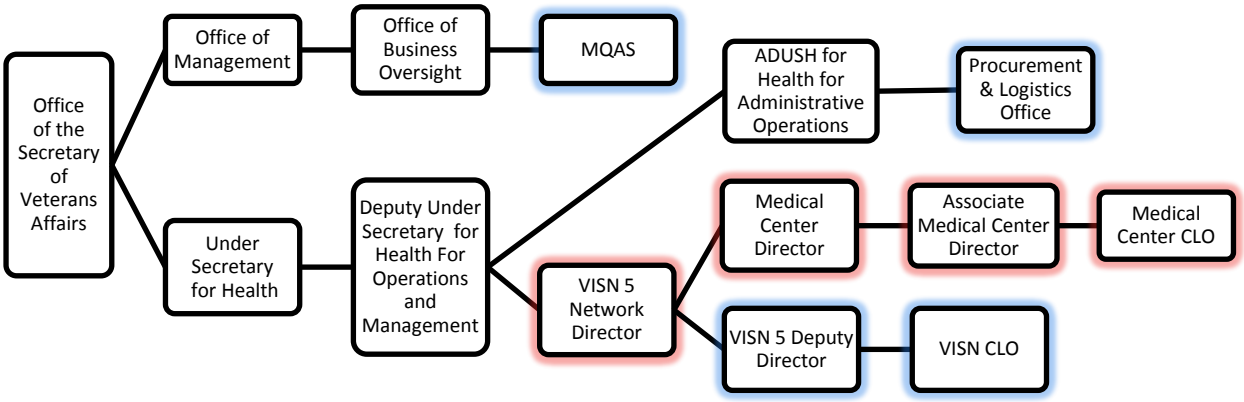
A VHA Procurement and Logistics Office program manager told OIG inspectors that the role of the Office was to act as a "middle man" between the Medical Center and MQAS to ensure that the Medical Center responses were sufficient for MQAS needs. He clarified that when MQAS issued a report, the Procurement and Logistics Office had an immediate role with respect to assisting the Medical Center to create an action plan that adequately responded to MQAS recommendations.[141] After the action plan was submitted to MQAS, the role was then limited to providing support when requested by either MQAS or the Medical Center. Upon reviewing the ongoing issues with the Medical Center in February 2017, the program manager acknowledged that effective follow-up and closure of recommendations required better coordination between MQAS and the Procurement and Logistics Office. As of February 2018, the responsibility for reviewing Medical Center adherence to VHA and VA Directives respecting logistics matters rests with the VHA Procurement and Logistics Office.

Figure 6 depicts the lines of authority that existed among MQAS, the VHA Procurement and Logistics Office, and the Medical Center.

[140] From May 2015 to January 2017, the Medical Center transitioned to an inventory system called Catamaran in lieu of GIP at the direction of the VHA Procurement and Logistics Office. During this time period, MQAS agreed to accept an alternative report generated by the Catamaran vendor to demonstrate use of an inventory management system. MQAS reviewed reports provided by the vendor and determined that irreconcilable errors in the reports rendered them insufficient for the purpose of verifying Medical Center adherence to VHA directives respecting the implementation of an inventory system. Although the Medical Center had nominally transitioned to Catamaran in May 2015, VHA Procurement and Logistics Office staff were aware by January 2016 that the Medical Center had reverted to its manual inventory management practices and was not using the Catamaran system. These staff told OIG inspectors that they had no authority over the Medical Center, could not compel it to comply, and did not escalate the matter to VHA Procurement and Logistics Office leaders.

[141] The "middle man" interpretation of the office's role appears inconsistent with the DUSHOM 2009 memo cited above that "P&LO will be responsible for *validation of action* indicated by the facilities as well as monitoring and reporting to this office and MQAS on completion of action" (emphasis added).

Figure 6. Lack of Reporting Relationship among MQAS, VHA Procurement and Logistics Office, and Medical Center*



Source: OIG analysis of VA Functional Organizational Manuals 2013–2017

**Boxes highlighted in red represent offices or individuals that had knowledge of both Logistics Service problems at the Medical Center and operational responsibility for addressing the problems. Boxes highlighted in blue represent offices or individuals that had knowledge of problems at the Medical Center, but no direct authority over Medical Center operations.*

(2) 2013 Network External Review Conducted by VISN 5 Identified Significant Deficiencies in the Logistics Service

Each VISN is required to conduct an annual review of its facilities' logistics operations.[142] On May 20, 2013, Mr. Rivera sent Mr. Hawkins a report of findings from a May 7–8, 2013 Network External Review (NER) relating to Logistics Service. The 2013 NER report contained 55 observations of noncompliance with VHA directives respecting nonexpendable and expendable inventory management. Chief among these observations was the finding that the Medical Center was not using GIP to manage its inventory. On June 13, 2013, Associate Medical Center Director Matthews responded to the 2013 NER report and provided estimated implementation dates for each of the 55 areas of noncompliance.

Available records at the time of the OIG's review were insufficient to determine the extent of efforts (if any) made to address the deficiencies identified in the 2013 NER report. Witnesses were either unavailable or lacked recollection sufficient to explain what corrective measures were undertaken. Nonetheless the key noncompliant conditions identified in the 2013 NER report, such as the nonuse of GIP, continued to exist at the time of the 2017 OIG inspection.

[142] Documentation shows that for 2014, the former VISN 5 CLO sought and obtained an exemption from the requirement to conduct an NER at the Medical Center. The reasons cited included an upcoming study of Logistics and the anticipated implementation of a new inventory management system.

(3) 2013 Consultant Report Identified SPS Deficiencies

In December 2013, a consultant provided findings of a review (2013 Consultant Report) after a site visit assessing the Medical Center Facility Management Service and Safety Programs. The 2013 Consultant Report was produced at the direction of VISN 5 and provided to Mr. Hawkins, Mr. Rivera, and Mr. Richardson. The report detailed numerous concerns, including that "the Sterile Processing Service (SPS), a high visibility program with critical responsibility toward patient safety, is working in an area that was identified to be outside of required environmental controls (humidity), and environmental monitoring is not being consistently or continuously conducted." In addition, the consultant noted that documentation of SPS staff competencies was not available. The OIG is unable to determine what remedial efforts were made, if any. Any improvements were not sustained because the SPS deficiencies identified in the 2013 Consultant Report persisted at the time of the 2017 OIG site visits.

(4) 2014 Logistics Study Identified Significant Deficiencies in the Supply Chain Management

VISN 5 engaged another external consultant to study Logistics Service operations within its facilities in 2014, which resulted in a November report (2014 Logistics Study). The 2014 Logistics Study was reviewed and circulated among Logistics Service professionals within the Medical Center, VISN 5, and the VHA Procurement and Logistics Office during 2015. On September 15, 2015, Mr. Matthews participated in a telephone presentation given by the Acting VISN 5 CLO, who presented the consultant's findings.

As a result of the consultant's observations, VISN 5 performed an analysis that identified two "high risk" conclusions with respect to Medical Center staffing. First, the Medical Center Logistics Service staffing for expendable supply management (12 employees) was significantly lower than similar facilities (35.9 employees). Second, the Medical Center had high staff vacancy rates in both the expendable supply (33 percent vacant) and nonexpendable equipment (50 percent vacant) Logistics Service.

The Medical Center CLO stated that he had sought to increase staffing for several years. His efforts were corroborated by contemporaneous emails and statements from other witnesses. These sources contended that the Medical Center CLO's efforts to hire staff were impeded by a lack of support from the Medical Center HR, which resulted in years-long efforts to adopt position descriptions and demonstrate necessary approvals for the advertising of open positions for hiring. A former Medical Center Logistics Service leader told OIG inspectors that he brought these impediments to the attention of Mr. Matthews and the Acting Medical Center Assistant Director in conversations and via email throughout 2015 and 2016, but that the issues were not remediated. OIG inspectors identified email threads corroborating the Logistics Service leader's effort to resolve HR issues so that the Medical Center could advertise these positions for hiring.

Mr. Hawkins acknowledged being aware of problems in HR,[143] which he attributed to the lack of stable HR leadership.[144] Mr. Hawkins told OIG inspectors that new positions were first approved by the RMC and that he was responsible for signing and approving the minutes to the RMC meeting. Documentation reflects that on August 18, 2015, the RMC approved hiring five Medical Supply Technicians for the Logistics Service. On January 14, 2016, HR reported that the minutes from the RMC meeting held on August 18, 2015, were "in the process of being signed" by Mr. Hawkins. HR obtained signed minutes on February 3, 2016. Despite the approval, the Logistics Service remained understaffed at the time of the OIG review.

(5) 2016 Review by VISN 5 Identified Significant Deficiencies in Availability of Nurses and Supplies

VISN 5 reviewed nurse staffing and related issues in its facilities in 2016. On May 16, 2016, Mr. Williams wrote to Mr. Hawkins reporting the results of the VISN 5 Nursing Service Review (2016 Nursing Report). Among the findings, the report noted that the Medical Center was short approximately 98 nurses, which was necessitating overtime work that VISN 5 characterized as unsafe and unsustainable. The report also stated that the "supply chain is broken from distribution of supplies to the nursing units to the ordering of specialty supplies for the OR and Critical Care Units — resulting in delays in patient care and diagnosis."

The 2016 Nursing Report stated that "because of safety concerns, immediate steps must be taken to control census such that the net effect will result in a minimum of 25–30 Medical-Surgical beds being unoccupied." On May 17, 2016, Mr. Hawkins responded to Mr. Williams, acknowledging more than 100 registered nurse (RN) vacancies and nearly 50 technician vacancies. He also wrote, "[e]ven with the current nursing staffing there have been no sentinel events at the medical center."

With respect to the supply chain issues, Mr. Hawkins wrote:

> *Catamaran POU (Point Of Use) Inventory Management System is in place with Kiosk's available on major Med/Surg Wards. Currently there are numerous amounts of variations of the same item being used*

[143] A former HR supervisor attributed the hiring delays to incompetence of her subordinate staff within HR management. She told OIG inspectors that she brought these concerns to the attention of Mr. Hawkins and the VISN, but that no action was taken to resolve the issue. Several other members of the Medical Center leadership also expressed doubt about the competency of clerks within HR. Mr. Hawkins summarized to OIG inspectors the "HR program, it was the pits, and I'm not going to sugarcoat that."

[144] Mr. Hawkins told OIG inspectors that he blamed VISN 5 for "interfering" in the management of the Medical Center HR; specifically, that VISN 5 terminated one HR chief during the probationary period and investigated a subsequently appointed HR chief. The OIG received no documentation or information to corroborate improper interference by VISN 5 other than Mr. Hawkins' allegations. To the contrary, the OIG learned VISN 5 had attempted to provide resources to assist the Medical Center with addressing its HR challenges from at least March 2015 to February 2017. These efforts were not successful.

> *by different clinical departments in the medical facility (color, Manufacturer). We anticipate full implementation of the Clinical Product Review Committee (CPRC) will reduce variation, assist in identifying appropriate par levels of standard items,[145] and reduce associated costs. Logistics continues to partner with nursing to enhance par level management of critical supplies. Clinical Nurse Managers are consulted to identify supply concerns. Daily House Wide check sheet for charge nurse to list and sign off on all supply concerns has been instituted. Although the medical supply staffing has experienced recent attrition, six Medical Supply Technician positions were approved for recruitment.*

Interviews confirmed that consistent with Mr. Hawkins' statement, nursing staff became responsible for communicating supply outages and setting normal stock levels for expendable supplies contrary to VA policy.[146] Inconsistent with Mr. Hawkins' statement, the Medical Center was not actually using the Catamaran system to manage its inventory.

(6) and (7) 2015 and 2016 NPOSP Reports Identified Significant SPS Deficiencies

In April and September 2015, members of the NPOSP conducted site visits to the Medical Center to review SPS and issued reports with a series of recommendations. As of April 24, 2016, the Medical Center reported that it had "closed" (satisfied) 25 of 28 recommendations arising out of the September 2015 site visit. The Medical Center reported that it planned to resolve two recommendations on or before May 20, 2016, and that the final recommendation relating to workflow would be addressed during a renovation of SPS planned for 2017. However, a repeat visit from NPOSP in October 2016 identified recurring issues previously reported as resolved, including environmental issues, lack of SOPs, and inadequate documentation of staff competencies. NPOSP issued additional recommendations, some of which were repeat findings from the 2015 visits.

In response to the October 2016 NPOSP recommendations, the Medical Center submitted another detailed action plan on December 9, 2016, with periodic progress updates thereafter. Documentation shows that the Medical Center updates falsely reported that some action items

[145] In documents and interviews, VHA personnel used the term "PAR level" (Periodic Automatic Replenishment) interchangeably with normal stock level, reorder point level, and emergency stock level. To reduce confusion, this report uses the latter three terms consistent with VHA Directive 1761(1) when not directly quoting interviewees.

[146] VHA Directive 1761(1). "VA was to [e]nsure that logistics staff, rather than clinical staff, manage all medical supplies."

identified in the NPOSP 2016 visit had been completed. For example, in October 2016 the NPOSP found the following:

- The Women's Health clinic lacked a dedicated soiled utility room. The Medical Center reported that it had resolved the issue on December 31, 2016. In April 2017, VISN 5 reopened this action item because it had not been corrected.
- The Master RME inventory list did not contain all critical and semi-critical RME in use at the Medical Center. The Medical Center reported to VISN 5 and the NPOSP that it had resolved the issue on November 18, 2016. In April 2017, VISN 5 reopened this action item because it had not been corrected.

In a progress update provided on January 17, 2017, the Medical Center reported to VISN 5 that it had satisfied these two action items.[147] This status update was compiled by the Acting Chief Nurse, who told OIG inspectors that she relied upon the representation of the Acting Chief of SPS that the action items had been appropriately addressed. She stated that at the time she did not have reason to believe that the representations were false, and therefore she did not independently confirm that the action items had been addressed. The OIG identified at least ten other improperly closed action items that were reopened by the VISN in April 2017. Subsequent to the April 2017 OIG site visits, the Medical Center began implementing a long-delayed plan (since at least FY 2011) to renovate its SPS areas. The renovation is designed to address some of the environmental, work flow, and capacity problems.

The chronic Medical Center deficiencies noted in the 2013–2017 reports outlined above speak to leaders' inability or unwillingness to implement and sustain lasting change within various services. For example, an effectively staffed SPS program has been lacking since at least 2015 with vacancies at the highest level. The Medical Center did not have a permanent Chief of SPS during the 2017 OIG visits and had three different Chiefs of SPS from May 2015 to March 2017.

The Medical Center Director and Associate Medical Center Director Provided Ineffective Leadership

As the Medical Center Director, Mr. Hawkins bore responsibility for the various managerial and administrative deficiencies that occurred under his leadership. Evidence shows that many of these deficiencies were elevated directly to Mr. Hawkins' attention, but were not effectively remediated.

Mr. Hawkins told OIG inspectors that the scope and depth of the Logistics Service issues were unknown to him until late January 2017 when he received a briefing following an inspection by

[147] VISN 5 personnel told OIG inspectors that the Medical Center was responsible for the accuracy of the content in the status update. VISN 5 provided the Medical Center update to the NPOSP on February 2, 2017.

the Policy Assessment and Quality group of the VHA Procurement and Logistics Office. After the briefing, Mr. Hawkins asked for assistance, which prompted the staff detail assignment of an acting CLO and several support personnel from different facilities.[148] Mr. Hawkins stated that he was aware of episodic supply shortages that he characterized as "onesies and twosies," which he viewed as typical. The explanation that these occurrences were of an isolated nature cannot be reconciled with the fact that Mr. Hawkins received multiple reports specifying significant systemic deficiencies in the Medical Center over a period of years starting no later than January 2013.

Medical Center Director Actions

During interviews, multiple Medical Center personnel described Mr. Hawkins' management style as exclusionary, nonresponsive, resistant and/or intimidating. VISN 5 Director Williams and other VISN 5 staff stated that it was at times difficult to obtain required information from the Medical Center. In general, perceptions are subjective and difficult to validate; however, emails, meeting minutes, and investigation transcripts reviewed by the OIG appeared to support these staff perceptions. In December 2016, according to Office of Accountability and Review documentation,[149] Mr. Hawkins was formally reprimanded for intimidating a subordinate employee by inappropriately confronting the employee about a report she made concerning workplace harassment and bullying allegedly perpetrated by Mr. Hawkins. As a result of this reprimand, Mr. Hawkins was penalized by a five percent reduction in base salary. The OIG team found no evidence of pending or completed disciplinary actions against Mr. Hawkins regarding the specific issues discussed in this report prior to his removal from his position in April 2017. VA fired Mr. Hawkins in September 2017.

The ineffectiveness of Mr. Hawkins' leadership is demonstrated by an interaction with Chief Nurse Barry, which Mr. Hawkins and others described as follows:

- *In May 2016, Ms. Barry disclosed during a meeting with Mr. Hawkins, Dr. Faselis, and others that she had recently learned that nursing staff had been stringing a type of gauze across a ward in an effort to prevent patient elopement—a practice that created a high risk to patient safety. Mr. Hawkins stated that Ms. Barry raised the issue as evidencing the impact of shortages in nursing staff. Mr. Hawkins recounted that his reaction was "I knew about this a month ago, and I'm concerned that you*

[148] Subsequent to receiving the January 2017 briefing from the VHA Procurement and Logistics Office, Mr. Hawkins chartered an Administrative Investigation Board to investigate the failings within the Logistics Service. Mr. Hawkins requested and received assistance from VHA in the form of Logistics experts temporarily detailed to the Medical Center. At the time of the OIG initial site visit in March 2017, the Medical Center had not made progress toward establishing an effective inventory management system, as detailed in the Interim Report.

[149] The Office of Accountability and Whistleblower Protection is the VA office that is now charged with providing investigative internal affairs services necessary to improve health, benefits, and cemetery needs for veterans.

> *didn't..." Mr. Hawkins stated that he disagreed with Ms. Barry's assessment that the issue was one of staffing, and instead, viewed it as a matter of improperly restraining patients. This interaction occurred within a few days of the 2016 Nursing Report in which the VISN concluded that nurse staffing levels at the Medical Center were unsafe, lending support to Ms. Barry's assessment.*

Other members of the Medical Center leadership team related similar stories of unproductive responses from Mr. Hawkins in response to problems raised to his attention. For example, a senior member of management told OIG staff that Mr. Hawkins accused the Chief of Surgery of being ineffective when the Chief of Surgery raised a concern about surgical supply problems during a 2015 or 2016 meeting. A second senior manager told OIG inspectors that she recalled an instance during another daily Morning Report meeting where the Chief of Surgery reported that a patient's surgery had been canceled due to an equipment issue. Mr. Hawkins wanted to know the identity of the staff person who contacted the patient. When the Chief of Surgery could not immediately answer the question, Mr. Hawkins became extremely agitated and shouted "clear the room," which was a cue for all of the other participants to immediately leave the meeting except for the Chief of Surgery.

Documentation reflected examples of Mr. Hawkins avoiding or dismissing concerns brought to his attention. For example, a December 2015 memorandum sent to Mr. Hawkins provides a detailed chronology of an unsuccessful 10-month effort to fill 61 vacancies in the nursing service. The memorandum indicates that the nursing service was not staffed at the recommended level and stated that "[i]mmediate management will require controlling inpatient census. Current staffing levels can support an overall inpatient occupancy rate of 71 percent without relying on voluntary or mandatory overtime." The memorandum reflects, and staff confirmed in interviews with OIG inspectors, that Mr. Hawkins did not meet to address the issues raised in the memorandum. Six months later, the 2016 Nursing Report from VISN 5 validated the conclusions stated in the memorandum.

Lack of Stable Leadership Regarding Associate Medical Center Director

The Medical Center has had five Associate Directors since 2013, most of whom assumed the role in an acting capacity. The Associate Director is responsible for the managerial and administrative services and operations that are the subject of this report, including Logistics Service, HR, Fiscal Service, and EMS. Mr. Matthews was the last permanently appointed Associate Director, and he served in this role until December 2015. The Medical Center administrative deficiencies persisted throughout his tenure, and documentation shows that information concerning the deficiencies was provided to Mr. Matthews. When interviewed by OIG staff, Mr. Matthews could not recall the logistics and supply chain inventory management deficiencies discussed throughout this report.

In the 15 months between Mr. Matthew's departure and the OIG site visits, the Associate Director role was filled on an acting basis by three other individuals. One of the Acting Associate Directors told OIG inspectors that relevant Medical Center and VISN leaders did not advise him/her about Logistics Service deficiencies nor was he/she provided with any of the reports reflecting the same. Lack of consistent leadership in this key role since December 2015 made it more likely that the Medical Center managerial and administrative deficiencies would remain unaddressed.

VISN 5 Leaders Failed to Take Adequate Corrective Action

In describing the VISN Director role, Mr. Williams stated that "requirements to execute are local," which he explained meant that Mr. Hawkins was responsible for assuring that Medical Center programs and processes were functional and compliant. Mr. Williams told OIG interviewers that the VISN responsibility should be to intervene when it has notice of a problem, and conceded that ultimately "the buck stops" with him (Mr. Williams).

The OIG determined that VISN 5 had notice of several significant problems since at least 2013, but failed to effect change at the Medical Center.

Failures to Address Insufficient Logistics Service Staffing

The fundamental flaws in the Medical Center Logistics Service were disclosed to Mr. Rivera and Mr. Richardson on January 18, 2013, when they received the MQAS Report. Mr. Rivera was included on subsequent follow-up email correspondence. Mr. Rivera issued the 2013 NER report to Mr. Hawkins that identified significant issues in the Medical Center Logistics Service.

Mr. Williams acknowledged knowing about the existence of Logistics Service and supply chain inventory management issues in the Medical Center since shortly after he arrived in 2015, when he received the 2014 Logistics Study in approximately May 2015. Among the key findings in the 2014 Logistics Study were that the Medical Center Logistics Service was understaffed and the Medical Center was not making appropriate use of GIP.

Mr. Williams told OIG inspectors that the follow-up relating to issues identified in the 2014 Logistics Study was being managed by Mr. Richardson. The OIG could not find evidence that the VISN took effective actions to resolve the staffing issues cited in the 2014 Logistics Study. Mr. Williams also told OIG inspectors that in April 2016 he became "re-aware" of the Logistics Service concerns and staffing issues during a "Town Hall" meeting he conducted at the Medical Center. Mr. Williams stated that as a result of the issues raised during the April 2016 Town Hall meeting, he ordered the VISN 5 Quality Management Officer to conduct the 2016 Nursing Report. Mr. Williams stated that as a result of the 2016 Nursing Report, the VISN provided the Medical Center with $2.8 million to address the issues.

During the April 2017 OIG visit, the VISN 5 CLO told OIG inspectors that soon after he took the position in May 2016, he became aware that the Medical Center had staffing challenges in its Logistics Service. He explained that he lacked authority over operational decisions made within the VISN facilities. Instead, his authority was limited to making advisory recommendations to the Medical Center and/or elevating concerns to Mr. Richardson, who could persuade Mr. Williams to exercise authority over a Medical Center Director to effect change. He stated that he spoke with the Medical Center CLO and Mr. Richardson about the inadequate Logistics Service staffing issue on multiple occasions throughout the fall of 2016. A former Acting VISN 5 CLO stated that in July 2015, just prior to leaving his post, he also had conversations with Mr. Richardson and Mr. Williams expressing concerns about the Medical Center Logistics Service staffing levels. The former Acting VISN 5 CLO did not recall whether action plans were put into place as a result of his conversations with Mr. Richardson and Mr. Williams.

Inadequate Metrics to Supervise Medical Center Logistics Service

VISN 5 used a color-coded scorecard to track compliance with VHA Logistics Service requirements related to both expendable supplies and nonexpendable equipment. For example, each Medical Center is required to annually account for the nonexpendable equipment itemized on its Equipment Inventory List (EIL).[150] VISN 5 tracks the percentage of nonexpendable equipment that has been accounted for by each of its facilities within the preceding 12 months (EIL Compliance). A facility that has accounted for at least 95 percent of its equipment is coded green, 90–94 percent is coded yellow, and less than 90 percent is coded red.[151]

Several individuals, including Mr. Hawkins and Mr. Richardson, stated that the Medical Center Logistics scorecard was "in the green" and therefore did not raise suspicions about the state of its Logistics Service. The OIG determined that some metrics on the scorecard, such as EIL Compliance were not always coded as green.[152] Even on the occasions that EIL Compliance was in the green, VISN and Medical Center leaders had information sufficient to cause them to place less reliance on the scorecard, including the findings of an external consultant issued in the 2014 Logistics Study.

In March 2015, the Acting VISN 5 CLO communicated the results of the 2014 Logistics Study to Logistics Service leaders in the VISN 5 facilities. Among other findings, the 2014 Logistics Study identified inadequacies in the scorecard and its data including "self-inflicted issues with

[150] VHA Directive 7002/1, *Inventory of Equipment in Use*, part 8, April 14, 2011.

[151] The metrics displayed on the VISN 5 Logistics Scorecard have changed over time. In addition to the nonexpendable EIL compliance discussed here, the VISN 5 Logistics Scorecard presents a color-coded display of metrics relating to expendable supplies, such as average stock turnover rate and average days of stock on hand.

[152] For example, for the entirety of FY 2014 the monthly VISN 5 Logistics Scorecard displayed red indicators for the Medical Center EIL Compliance, reflecting that the Medical Center had not met its annual equipment inventory obligation.

data integrity" that caused management to have an "unreliable perspective of the supply chain."[153]

One example of a self-inflicted data integrity problem occurred after the 2014 Logistics Study was published. In November 2015, an unauthorized database update reset the Medical Center EIL Compliance to 100 percent, which was false. In February 2017, the Medical Center CLO testified that in November 2015 he knew that there was "no way humanly possible we're 100 percent compliant." He stated that he raised the reset issue with the Acting VISN 5 CLO in November 2015, but that no one could reverse the erroneous update. Because the Medical Center is only required to count a piece of equipment once in any 12-month period, this error had the impact of causing the Medical Center scorecard EIL compliance to show green (that is, 100 percent of items were counted) through November 2016 irrespective of whether the equipment had actually been counted within the preceding 12 months.[154]

According to the VISN 5 CLO interviewed by the OIG in September 2017, some of the data integrity issues identified in 2014 persisted. The CLO attributed the persistent issues to the lack of a permanent VISN 5 CLO from March 2015 to June 2016 as well as significant VHA Procurement and Logistics Office projects from summer 2016 to summer 2017.[155] He further stated that recent efforts to correct the data integrity issues resulted in a $65 million downward correction of reported inventory for VISN 5 facilities and the removal of 89,000 inactive vendors from GIP. These efforts have been underway since July 2017 and remain ongoing at this writing.

The 2014 Logistics Study also cautioned that strategic decision-making was undermined by the "underuse and little understanding of reporting tools, dashboards and metrics." [156] Consistent with this concern, when OIG inspectors asked Mr. Hawkins to explain the meaning of the various VISN 5 logistics scorecard metrics upon which he relied, he was unable to do so.

The use of inadequate data jeopardized the VISN's ability to effectively oversee its facilities because serious deficiencies could go undetected. In this instance, however, independent reports

[153] The 2014 Logistics Study further elaborated that staff and processes were not aligned to enable use of the technology. The staff were not trained to correctly input and extract data from inventory management systems; staff and leaders did not use or know how to interpret GIP reports; informal processes had replaced GIP; manual entry between warehousing and inventory management systems led to the increased potential for errors; discrepancies between systems occurred; and controls to ensure or validate data integrity did not exist.

[154] The VISN 5 CLO told OIG inspectors that he discussed his concern with the Medical Center CLO in fall 2016 that the Medical Center was not on track to account for all of its equipment as required. The Medical Center CLO acknowledged the requirement, but stated that he did not have staff to perform the inventory. The VISN 5 CLO stated that he discussed the staffing issue with Mr. Richardson.

[155] The projects included a prime vendor transition, Catamaran to GIP migration, and rollouts of the new VHA Strategic Equipment Plan Guide and the Electronic Equipment Request Portal.

[156] The 2014 Logistics Study also identified that the scorecard lacked "critical metrics" for cost, cycle time, and order fulfillment.

(from MQAS and others) were sufficient to notify the VISN of problems in the Medical Center notwithstanding any data integrity problems.

VHACO Offices Sometimes Lacked Authority or Failed to Effectively Intervene

VHACO sets policy, implements programs, and provides support to VA medical facilities nationwide. Except in special circumstances, the day-to-day operational decisions of a medical center are the province of the medical center and its VISN, not VHACO offices and other divisions. Nonetheless, offices within VHACO receive information daily from medical centers and VISNs to inform national policy making. When a program office receives information regarding persistent and significant deficiencies, VA's expectation is that the program office will notify a responsible official who can take action to remedy the deficiency.

VHACO Program Offices' Awareness of Problems and Authority to Act

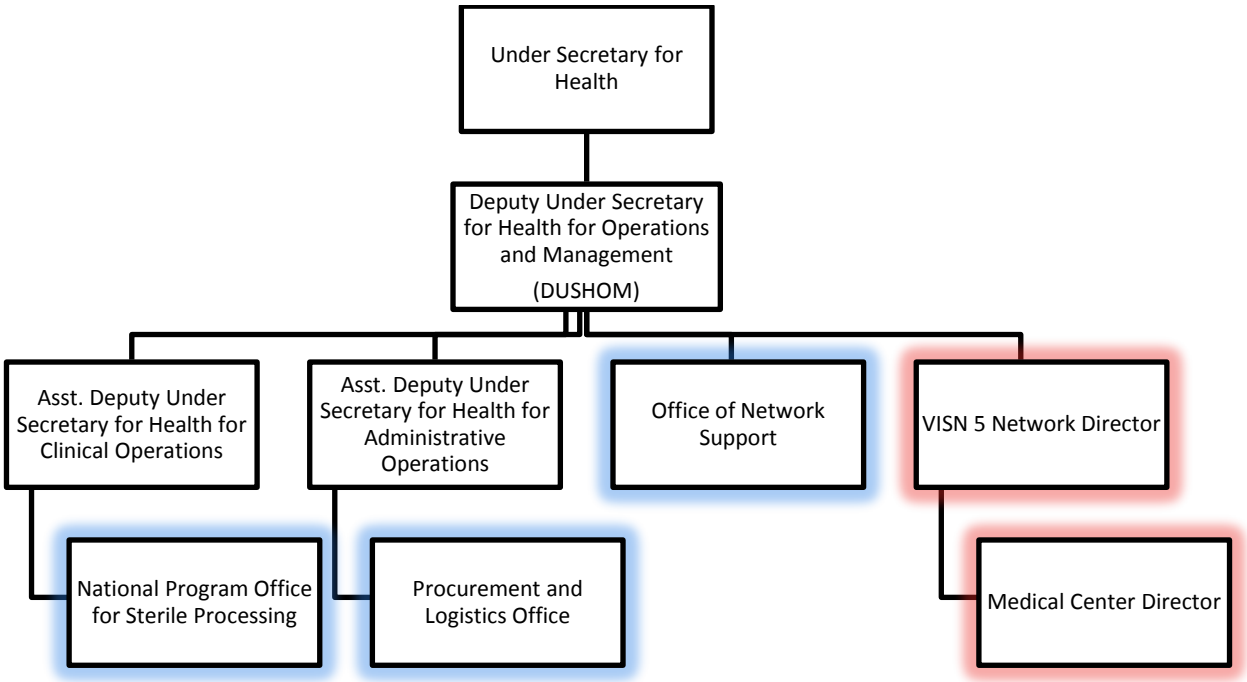
With respect to the managerial and administrative deficiencies at the Medical Center outlined in this report, at least three Program Offices—the Office of Network Support,[157] NPOSP, and the VHA Procurement and Logistics Office—had information sufficient to inform the Under Secretary for Health (USH) that serious, persistent deficiencies existed within the Medical Center that could potentially impact patient care. In a 2017 interview with OIG staff, VA Secretary David Shulkin indicated that when he was the USH from March 2015 to February 2017, he expected significant issues involving patient harm or operational deficiencies to be raised through the "usual" communication process.[158] Secretary Shulkin told interviewers he does not recall senior leaders' bringing issues at the Medical Center relating to supplies, instruments, and equipment to his attention while he was the USH.

Each of the three identified Program Offices reported to different officials, who reported through the Deputy Under Secretary for Health for Operations and Management (DUSHOM) to the USH (see Figure 7).

[157] VA 2017 Functional Organization Manual – v4.0. The Office of Network Support (10NA3) serves as a central organizing unit between field facilities, VISNs, medical centers, and VHACO. It manages information flow and knowledge sharing with VHA offices and provides consultative advice to leadership at all levels of VA and VHA regarding sensitive and complex issues related to healthcare system operations and management.

[158] According to guidance issued from the Office of the DUSHOM, the usual process involves medical centers' submitting issue briefs through their VISN to the Office of Network Support. The Office of Network Support disseminates the issue briefs within the Office of the DUSHOM, which can elevate issues directly to the USH. The Office of Network Support can also identify issues of particular concern for elevation to the USH.

Figure 7. Relevant Program Offices and VISN 5 Lines of Supervision*



Source: OIG analysis of VA 2013–2017 Functional Organizational Manuals

**Boxes highlighted in red represent offices or individuals with both knowledge of problems at the Medical Center and operational responsibility for addressing the problems. Boxes highlighted in blue represent offices or individuals with knowledge of problems at the Medical Center, but no direct authority over Medical Center operations.*

The Office of Network Support reports directly to the DUSHOM. According to VHA guidance, this office "is the primary source of information regarding VHA operational activity."[159] It is charged with maintaining "situational awareness through the ability to access information, anticipate critical information requirements, determine necessary follow-up actions for the facility, VISN, [VHACO] and/or Leadership by sharing information regarding situations, untoward events and issues of potential interest to the [VA Secretary]."[160]

The Office of Network Support receives numerous issue briefs on a daily basis.[161] Office of Network Support health system specialists catalogue, track, and disseminate the issue briefs to interested parties in VHA as necessary, using an issue tracker. In September 2015, guidance was disseminated from the DUSHOM's office to VISNs regarding which issues should be reported

[159] VHA, "10N Guide to VHA Issue Briefs," memo, p. 22, disseminated to VISN Directors on September 23, 2015.
[160] VHA, "10N Guide to VHA Issue Briefs."
[161] Issue briefs are communication tools generated in medical facilities to report significant conditions (for example, the closure of service) and channeled to the Office of Network Support by VISN personnel.

using issue briefs, and how this information would be used and disseminated within VHACO. Specifically, this guidance required the Office of Network Support to submit a weekly critical incident report to VHA Senior Leadership. VHA defined critical incidents to include issues involving access to or delays in care.[162]

An Office of Network Support staff member informed the OIG that issue briefs were sent to an email group (the 10N Action Group), which included both the Assistant Deputy Under Secretary for Health for Administrative Operations (Ms. Tammy Czarnecki) and the Assistant Deputy Under Secretary for Health for Clinical Operations (Dr. Thomas Lynch). After dissemination to the 10N Action Group, the Director of the Office of Network Support selects specific issue briefs to elevate to the attention of the USH. When interviewed, then Acting VHACO Chief of Staff did not recall receiving issue briefs referencing Medical Center "specific supply chain issues" for the 2015–2017 time frame.

While VHA guidance specifies that the Office of Network Support is responsible for disseminating information so that follow-up actions for VHACO, VISN, and medical center officials can be identified, VHA's guidance on 10N issue briefs does not specify who is responsible for determining that follow-up actions have taken place. This led to inconsistent follow-up, with some program offices reporting their findings to senior officials through issue briefs, and others not elevating unresolved issues, as the following two examples illustrate:

- *First, the OIG determined that the Medical Center submitted an issue brief to the Office of Network Support that related the findings of the NPOSP October 2016 report (insufficient staffing, lack of SOPs, and inadequate documentation of competencies) and indicated that an action plan was being developed. The issue brief included references to repeat findings related to lack of SOPs and staff competencies among others.*

  The Medical Center submitted the NPOSP October 2016 action plan on December 9, 2016. The OIG did not find evidence that VHACO leaders other than NPOSP followed up on the findings in the 2016 report, and many of the conditions described in that issue brief persisted throughout the OIG's 2017 inspection.

- *Second, MQAS informed VHA Procurement and Logistics Office staff about the Medical Center's underutilization of GIP as early as 2014, and requested their assistance in resolving outstanding recommendations. While the Medical Center subsequently transitioned to Catamaran in May 2015, the VHA Procurement and Logistics Office staff were also aware by*

[162] VHA, "10N Guide to VHA Issue Briefs, p. 9."

> *January 2016 that the Medical Center had reverted to its manual inventory management practices and was not using the Catamaran system. These staff told OIG inspectors that they had no authority over the Medical Center, could not compel it to comply, and did not escalate the matter.*

Because many program offices do not have clear lines of authority or responsibility over medical center operations, it is vital that program offices routinely communicate important site visit findings, and particularly recommendations that have gone unaddressed for long periods, to those leaders within VHACO who directly oversee medical center and VISN operations and can effect change. Good communication is also necessary for ensuring that VHACO officials have the ability to verify that problems have been resolved.

Recommendations 33–36

Recommendation 33. The Deputy Under Secretary for Health for Operations and Management ensures that the VHA Procurement and Logistics Office conducts regular audits of the logistics services within VHA medical centers to assess compliance with VA and VHA policies pertaining to procurement and logistics, and makes certain that timely and effective remediation occurs in response to all noncompliant conditions identified as a result of those audits.

Recommendation 34. The VISN 5 Director evaluates the accuracy of representations made by Medical Center staff in connection with the completion of action plans arising out of the National Program Office of Sterile Processing October 2016 site visit and determines whether administrative actions should be taken as a result of those representations.

Recommendation 35. The VISN 5 Director institutes procedures designed to ensure the accuracy of future representations made by Washington DC VA Medical Center staff in connection with action plans submitted to oversight bodies such as VHA program offices.

Recommendation 36. The Under Secretary for Health clearly defines program offices' responsibility for reporting high-priority recommendations to responsible individuals within VHACO, and requires independent verification that the relevant medical center and/or VISN have implemented the recommendations.

Lack of VHACO Practices to Proactively Aggregate and Analyze Available Data

Multiple VHA offices collect information that could be used to detect trends or problems. As noted in this report, these offices included MQAS, NCPS, NPOSP, Office of Network Support, and the VHA Procurement and Logistics Office. The OIG learned from the VISN 5 CLO that other data existed that could have been used to detect some of the Logistics Service issues. For example, GIP transaction volume data, readily available in the Corporate Data Warehouse (the

VA repository for data), could be used to identify facilities that may not be making appropriate use of GIP.

The OIG acknowledges that significant volumes of data were collected relating to the issues at the Medical Center and that individual VHA program offices used that data in accordance with their missions. For example, the NPOSP collected information about the state of the Medical Center SPS program and conducted repeated inspections to address recurrent issues. However, follow-through by the VHA program offices and VISN 5 was neither timely nor effective because the failing conditions persisted or recurred in the Medical Center Logistics and the Sterile Processing Services for multiple years. Also missing was an integrated approach that could have potentially identified broader Medical Center leadership issues that become apparent by assembling the disparate data points available to VHA from 2013 to 2016 (for example multiple NPSOP, MQAS, Procurement and Logistics Office findings; various other prior findings chronicled in this report; and reports to NCPS).

The VHA Office of Quality, Safety and Value utilizes a database named Findings Aggregation Categorization & Trending System (FACTS) to compile information relating to the oversight of VHA facilities. The OIG team viewed the FACTS record for the Medical Center; it contained information from issue briefs, Joint Commission findings, and OIG reports from FY 2014 through April 24, 2017. Other significant data points were absent, including references to the 193 supply-related patient safety reports received by NCPS from the Medical Center during the same time period. The FACTS report contained no references to the results of the seven significant reports detailed above (see also, Appendix B: Relevant Reports). The OIG team was told that VHA's use of the FACTS database has been limited to reactive situations, such as gathering information about a medical center to assist VHA leaders in responding to a public relations crisis. VHA has not used FACTS to proactively monitor facilities or VISNs and has no established requirement that an office conduct such proactive data aggregation and analysis.

Failed Migration to Catamaran Inventory System

In April 2014, VHA began a planned national transition from GIP to the Catamaran Point of Use Inventory System (Catamaran). The transition, however, was not permanent and VHA returned to using GIP after the Catamaran contract ended on February 28, 2017. During the OIG review of supply, instrument, and equipment issues at the Medical Center, the OIG received concerns that medical centers in Baltimore, Maryland, and Pittsburgh and Philadelphia, Pennsylvania, were experiencing similar supply chain inventory management disruptions. These disruptions were largely associated with the transition from Catamaran back to GIP. The OIG deployed a Rapid Response Team to assess whether conditions in the other facilities warranted a full-scale review.

The OIG learned that VHACO Logistics Service personnel had visited these medical centers in April and May 2017, and were aware that supply disruptions were occurring. The OIG

determined that the other three medical center directors had developed plans and begun to remediate supply chain inventory management challenges, and therefore the OIG did not conduct further reviews at those locations. For one of the three medical centers, the Procurement and Logistics Office independently assessed its corrective action plan to determine adequacy.

OIG identified two challenges in the implementation of Catamaran that could have been avoided. First, the lack of reporting ability in Catamaran caused unnecessary "blind spots" for oversight. Prior to Catamaran, Logistics Service personnel in medical centers and VISNs relied on stock status metrics that GIP reported. Catamaran did not provide VISNs with the same reporting capabilities. The VISN 5 Materiel Manager told OIG inspectors that stock status and related reports for each facility could no longer be accessed directly by VISN staff and instead had to be requested from the Catamaran vendor via VHA Procurement and Logistics Office, but flaws in the data rendered the reports unreliable. For example, the unit measures (cases vs. individual items) were often incorrect, which had the effect of appearing to overstate or understate inventory levels.[163]

Another "blind spot" specific to the Medical Center related to the ongoing follow-up effort conducted by MQAS personnel. MQAS continued to request reports sufficient to demonstrate certain stock status metrics, but Medical Center Logistics Service personnel did not provide these reports. Instead Medical Center Logistics Service personnel claimed that Catamaran was incapable of generating the required information. After confirming with the Procurement and Logistics Office, MQAS held its request in abeyance until December 2015, at which time it resumed requesting the required reports. Neither the Medical Center nor the VHA Procurement and Logistics Office could generate the requested reports when MQAS resumed its requests. Email threads show that the Procurement and Logistics Office was aware of the reporting deficiencies, but that the Catamaran program was canceled before the report reliability issues were resolved.

Second, facilities were not adequately supported in their transition back to GIP after Catamaran was unexpectedly canceled. Staff at each of the three medical centers complained that communication from the Procurement and Logistics Office concerning the conversion back to GIP lacked essential details needed to plan for an effective transition. Facility staff were saddled with unforeseen, time-consuming manual data entry and other demanding tasks, but no additional staffing was provided. One facility reported that it unexpectedly exhausted its

[163] The OIG observed in documentation and confirmed in interviews that irrespective of the lack of automated reporting from Catamaran, VHA Procurement and Logistics Office personnel were aware that the Medical Center was not actually using the Catamaran system to manage its inventory. The OIG did not identify communications between the Procurement and Logistics Office and VISN personnel that disclosed the Medical Center's nonuse of the Catamaran system.

overtime budget for the entire year as a result. The transitions to GIP began in January 2017, but none of the facilities were 100 percent operational with GIP during OIG site visits in May 2017.

These problems contributed to the failings found at the Medical Center and undermined VISN 5's ability to monitor Logistics Service metrics in its facilities. VISN 5 was aware that the Medical Center was not using GIP prior to the Catamaran implementation, but during the Catamaran implementation the unavailability of reliable reporting prevented VISN 5 from being able to effectively supervise the Medical Center use or nonuse of Catamaran. The VISN 5 Materiel Manager reported speaking with Medical Center staff about inventory numbers that seemed too low, and that rather than admit that they were not using the Catamaran system, the Medical Center staff cited technical difficulties with the reporting. This explanation was credible because technical difficulties with the reports were occurring. Although the problems at the Medical Center predated implementation of Catamaran, this temporary blind spot created sufficient distraction to allow the Medical Center to continue to persist in a noncompliant state with limited scrutiny.

VHA Star Rating System

VHA uses the Strategic Analytics for Improvement and Learning (SAIL) model to summarize a medical center's performance. SAIL evaluates criteria "such as death rate, complications, and patient satisfaction, as well as overall efficiency and physician capacity" to arrive at a star rating between 1 and 5 (highest). The Medical Center maintained a 2-star (slightly below average) rating from 2011 through the third quarter of FY 2015, and then improved to a 3-star (average) rating, maintaining that rating through March 31, 2017.

The improvement in the Medical Center star rating was related to efforts of clinicians at the Medical Center and experts from the VHA Office of Analytics and Reporting who educated the Medical Center staff about the metrics that factor into the star rating. Medical Center leaders implemented clinical practice changes designed to improve those metrics by reducing patient risk of death while hospitalized, including sepsis protocols and early administration of antibiotics in Emergency Departments.

The factors considered in formulating a star rating generally focus on clinical measures, such as infection rates. One domain, the Efficiency Domain, considers specific administrative areas but

does not include supply chain inventory management and logistic issues,[164] even though such functions have clinical impact.[165]

As evidenced by the efforts made to improve the Medical Center star rating, the SAIL model incentivizes facilities to take action to improve the quality of care. However, SAIL's minimal focus on administrative functions that support patient care can leave patients vulnerable as reflected throughout this report.

Recommendation 37

The communication channels, databases, dashboards, and performance measure models discussed above and throughout this report did not provide a proactive, integrated, and "global" perspective on this Medical Center's failing operations across multiple clinical and administrative services. Because such a structure is lacking at the VHACO level, OIG makes the following recommendation:

Recommendation 37. The Under Secretary for Health develops a means of aggregating and analyzing available data on Logistics, Sterile Processing, Prosthetics, and Human Resources services (or other services as the Under Secretary for Health deems appropriate) so that major operational deficiencies at a medical center or VISN that affect multiple services or functions may be detected and corrected.

Recommendations 38–40

Because leaders at multiple levels had received information describing the many issues within the Medical Center on multiple occasions from January 2013 through January 2017, as well as the OIG 2017 findings, OIG makes the following recommendations:

Recommendation 38. The Under Secretary for Health takes appropriate administrative action to address the conditions identified in this report.

Recommendation 39. The VISN 5 Director oversees implementation of recommendations directed to the Medical Center Director.

Recommendation 40. The Under Secretary for Health verifies the successful implementation of all recommendations contained within this report.

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[164] See generally, Government Accountability Office, *Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety*, GAO-11-391, May 2011. *The Veterans' Access, Accountability, and Choice Act of 2014* required VHA to convene a national panel of independent experts to address challenges confronting VA in 12 key areas, including supply chain management.

[165] In addition to the potential for adverse clinical outcomes, avoidable delays and cancellations associated with SPS or supply chain inventory management failures impact the convenience and quality of care received by veterans, some of whom travel long distances to seek care from a VA hospital.

Conclusion

It was difficult to pinpoint precisely how the conditions described in this report could have persisted at the Medical Center for so many years. Rather than a single cause, a series of systems failures resulted in chronic understaffing; lack of critical controls over purchases and the management of supplies, equipment, and inventory; inadequate security and maintenance of physical facilities; and breakdowns in oversight and accountability.

Effective oversight of supplies, instruments, and equipment to clinical areas is not a paperwork exercise. Logistics, Sterile Processing, Prosthetics, Patient Safety, Fiscal, Environmental Management, and HR services assist in the effective delivery of health care to veterans. Deficiencies in those support functions can impact care provided in the OR, the Emergency Department, or other inpatient or outpatient care settings. The sheer magnitude and diffuse nature of the impact may paradoxically obscure the problems, whereas a deficiency in a single service might have been more apparent.

Leaders were repeatedly made aware of persistent problems. At the core, the OIG noted an unwillingness or inability of leaders to take responsibility for the effectiveness of their programs and operations. The OIG found that a culture of complacency and a sense of futility pervaded offices at multiple levels.

Through interviews, senior leaders and staff attributed problems to the complexity of federal laws and regulations governing acquisitions, procurement, contracting, and hiring; policy changes that occurred elsewhere within VA that were beyond their control; or failures of other leaders and managers. Some leaders claimed they were unaware of the magnitude of problems before the issuance of the Interim Report. While many factors may have contributed to the persistence of supply, instrument, and equipment issues and fiscal mismanagement at the Medical Center, senior leaders at all levels had a responsibility to ensure that patients were not placed at risk regardless of structural, process, or managerial impediments.

That the OIG did not identify adverse clinical outcomes was largely due to the efforts of personnel on the front lines of the Medical Center to borrow or otherwise quickly obtain what they needed, or improvise, in order to provide care to patients. The repeated exposure of patients to risk of an adverse clinical outcome and the squandering of taxpayer funds that resulted from persistent leadership failures within the Medical Center is unacceptable.

For the necessary improvements to be made, there must be close oversight and clear lines of responsibility for ensuring that all recommendations for improvement are implemented within a year of this report’s release or as agreed upon by the OIG and VA.

Recommendations

Recommendation 1. The Washington DC VA Medical Center Director ensures that necessary supplies, instruments, and equipment are available in patient care areas at the Medical Center when and where they are needed.

Recommendation 2. The Washington DC VA Medical Center Director requires operating room staff to conduct the final validation that all supplies, instruments, and equipment needed to perform the planned procedure and to address potential complications are in the operating room and available for use.

Recommendation 3. The Washington DC VA Medical Center Director makes certain that the operating room staff have accurate lists of surgical instruments needed for particular procedures.

Recommendation 4. The Under Secretary for Health specifies criteria under which individual medical centers will conduct wild card Aggregated Reviews for high-frequency patient safety events.

Recommendation 5. The Washington DC VA Medical Center Director ensures that routine audits of incident reporting system entries are completed to ascertain that all patient safety events are in the National Center for Patient Safety database as required by Veterans Health Administration policy.

Recommendation 6. The Washington DC VA Medical Center Director requires Medical Center oversight committees to follow up and initiate action as necessary on quality assurance matters related to supplies, instruments, or equipment.

Recommendation 7. The Washington DC VA Medical Center Director confirms the full utilization of a Veterans Health Administration-authorized inventory system that contains accurate and reliable information regarding the availability of supplies throughout the Medical Center.

Recommendation 8. The Washington DC VA Medical Center Director makes certain that the environmental integrity of clean/sterile storerooms complies with Veterans Health Administration policy.

Recommendation 9. The Washington DC VA Medical Center Director ensures there are clearly defined and effective procedures for replacing missing or broken instruments, and that staff responsible for this function have been educated on the process.

Recommendation 10. The Washington DC VA Medical Center Director confirms that clearly defined and effective procedures address the disposition of discolored instruments during reprocessing and that staff responsible for this function have been educated on the process.

Recommendation 11. The Washington DC VA Medical Center Director ensures that the Sterile Processing Service implements a quality assurance program to verify the cleanliness, functionality, and completeness of instrument sets prior to their reaching clinical areas.

Recommendation 12. The Washington DC VA Medical Center Director makes certain that Sterile Processing Service and operating room personnel comply with policies and procedures for the proper reprocessing of loaner instruments and trays.

Recommendation 13. The Washington DC VA Medical Center Director verifies that Sterile Processing Service managers maintain an accurate Master List for reusable medical equipment and file copies of manufacturer's instructions as required by Veterans Health Administration policy.

Recommendation 14. The Washington DC VA Medical Center Director ensures that the Sterile Processing Service maintains updated and readily accessible standard operating procedures for all instruments and equipment within Sterile Processing Service and its satellite areas in accordance with Veterans Health Administration policy.

Recommendation 15. The Washington DC VA Medical Center Director verifies that all Sterile Processing Service employees have appropriate, updated competencies and a demonstrated proficiency to perform their assigned duties.

Recommendation 16. The Veterans Integrated Service Network 5 Director secures adequate space and funding for the Washington DC VA Medical Center satellite reprocessing areas, which includes separate decontamination, processing, and packaging areas in accordance with Veterans Health Administration Sterile Processing Service policies.

Recommendation 17. The Veterans Integrated Service Network 5 Director makes certain that the Washington DC VA Medical Center Director resolves open and pending prosthetic consults and implements a plan to address future prosthetic consults in accordance with Veterans Health Administration policy.

Recommendation 18. The Washington DC VA Medical Center Director ensures the revision of Medical Center Fiscal Service practices to eliminate unnecessary cessations of prosthetic device purchasing, including at fiscal year-end.

Recommendation 19. The Veterans Integrated Service Network 5 Director, together with Washington DC VA Medical Center leaders, develops a staffing plan to fill vacancies that includes accurate numbers of authorized positions by service that is based on clinical and administrative workload and other appropriate measures, and includes contingencies for staffing areas with high attrition rates.

Recommendation 20. The Veterans Integrated Service Network 5 Director ensures the timely completion of hiring actions at the Washington DC VA Medical Center until staffing deficiencies in Logistics Service and Sterile Processing Services are fully resolved.

Recommendation 21. The Washington DC VA Medical Center Director transitions purchase cards held by clinical staff and used for expendable medical supplies to Logistics Service staff, while ensuring that medical supplies can be obtained in a timely manner.

Recommendation 22. The Washington DC VA Medical Center Director ensures that medical supply items are added to the prime vendor formulary in order to meet prime vendor purchasing goals.

Recommendation 23. The Washington DC VA Medical Center Director makes certain that the Purchase Card Coordinator and approving officials monitor the issuance and future use of government purchase cards in accordance with VA Financial Policy.

Recommendation 24. The Washington DC VA Medical Center Director maintains segregation of duties between personnel who order and purchase expendable and nonexpendable items and those who receive the items.

Recommendation 25. The Veterans Integrated Service Network 5 Director ensures that the Washington DC VA Medical Center updates and maintains the Equipment Inventory List as required by VA policy and makes certain that the Washington DC VA Medical Center Director and Chief Logistics Officer are held accountable for the timely and accurate reporting of the Washington DC VA Medical Center Equipment Inventory List.

Recommendation 26. The Washington DC VA Medical Center Director ensures that equipment is accurately and timely entered into the Automated Engineering Management System/Medical Equipment Reporting System.

Recommendation 27. The Washington DC VA Medical Center Director ensures that unrequired equipment is turned-in for disposition consistent with Veterans Health Administration policies and procedures.[166]

Recommendation 28. The Washington DC VA Medical Center Director properly secures all areas used to store medical equipment and supplies.[167]

Recommendation 29. The Washington DC VA Medical Center Director designates an official records manager, alternate records manager, and official records liaisons as well as implements a records management program in accordance with the National Archives and Records Administration requirements.

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[166] This recommendation is consistent with the Interim Report recommendation that "[t]he Under Secretary for Health takes all appropriate steps to ensure that the Washington DC VA Medical Center and Veterans Integrated Service Network arrange for the orderly movement of goods and supplies from the warehouse that minimizes losses to the Government."

[167] This recommendation also builds on the Interim Report recommendation that "[t]he Under Secretary for Health take immediate action to create an inventory and establish accountability over the equipment and supplies in the off-site warehouse."

Recommendation 30. The Washington DC VA Medical Center Director verifies that actions have been taken to notify patients when their information may have been improperly accessed, as appropriate.

Recommendation 31. The Washington DC VA Medical Center Director verifies that accurate and complete financial documentation to support medical supply and equipment purchases is readily available in accordance with GAO *Standards for Internal Control in the Federal Government*.

Recommendation 32. The Veterans Integrated Service Network 5 Director audits a representative sample of FY 2017 Washington DC VA Medical Center supply, instrument, and equipment purchases and ensures adequate internal controls for future purchases are in place.

Recommendation 33. The Deputy Under Secretary for Health for Operations and Management ensures that the Veterans Health Administration Procurement and Logistics Office conducts regular audits of the logistics services within Veterans Health Administration medical centers to assess compliance with VA and Veterans Health Administration policies pertaining to procurement and logistics, and makes certain that timely and effective remediation occurs in response to all noncompliant conditions identified as a result of those audits.

Recommendation 34. The Veterans Integrated Service Network 5 Director evaluates the accuracy of representations made by Washington DC VA Medical Center staff in connection with the completion of action plans arising out of the National Program Office of Sterile Processing October 2016 site visit and determines whether administrative actions should be taken as a result of those representations.

Recommendation 35. The Veterans Integrated Service Network 5 Director institutes procedures designed to ensure the accuracy of future representations made by Washington DC VA Medical Center staff in connection with action plans submitted to oversight bodies such as Veterans Health Administration program offices.

Recommendation 36. The Under Secretary for Health clearly defines program offices' responsibility for reporting high-priority recommendations to responsible individuals within Veterans Health Administration Central Office, and requires independent verification that the relevant medical center and/or Veterans Integrated Service Network have implemented the recommendations.

Recommendation 37. The Under Secretary for Health develops a means of aggregating and analyzing available data on Logistics, Sterile Processing, Prosthetics, and Human Resources services (or other services as the Under Secretary for Health deems appropriate) so that major operational deficiencies at a medical center or Veterans Integrated Service Network that affect multiple services or functions may be detected and corrected.

Recommendation 38. The Under Secretary for Health takes appropriate administrative action to address the conditions identified in this report.

Recommendation 39. The Veterans Integrated Service Network 5 Director oversees implementation of recommendations directed to the Washington DC VA Medical Center Director.

Recommendation 40. The Under Secretary for Health verifies the successful implementation of all recommendations contained within this report.

Appendix A: Scope and Methodology

This appendix describes the scope and methodology used to complete the OIG Interim Report and this final report.[168] It represents the consolidated work of the OIG Offices of Investigations, Audits and Evaluations, Healthcare Inspections, and Counselor to the Inspector General.

On March 21, 2017, the OIG received a confidential complaint describing equipment and supply issues at the Medical Center that posed a potential risk to patient safety. The complaint also described deficiencies that could place government assets at risk. In broad categories, the allegations included

- Lack of an accurate inventory resulting in
    - Supplies and equipment not being available to providers and patients when and where they were needed, and
    - Recalled supplies and equipment not being readily trackable;
- Storage areas not being clean and medical supplies and instruments not stored properly, thereby compromising sterility of the items;
- Massive stock of noninventoried supplies and equipment in an off-site warehouse; and
- Excessive purchase card use of supplies and equipment with minimal oversight or accountability.

Interim Report

To assess the allegations, an OIG Rapid Response Team conducted site visits on March 29–30 and April 4–6, 2017. The team conducted relevant document reviews (including those related to the off-site warehouse), inspected clean/sterile storerooms, and reviewed patient safety event information entered into the NCPS database from January 1, 2014, through March 29, 2017, related to supply, instrument, or equipment issues. The team also reviewed emails received through interviews and contacts from the Medical Center, reports from GIP (the VHA-authorized software program used by VA medical facilities to manage the receipt, distribution, and maintenance of supplies), and internal VA reports regarding the Medical Center Logistics Service.

[168] Some previous sections of this report include information related to the scope and methodology used to evaluate the topics discussed. That information from the narrative is not repeated in this appendix.

The OIG team interviewed Medical Center and VISN 5 leaders as well as Medical Center physicians, nurses, supply technicians, SPS technicians, HR personnel, administrative officers, and other knowledgeable staff.

During initial site visits, the OIG team confirmed many of the deficiencies described by the complainant and identified additional work required to fully assess the conditions. Because of a potential ongoing risk to patients, the OIG released an Interim Report on April 12, 2017. The report helped to inform VA, Congress, and the public about these risks; noted vacancies in key services that could impede remediation efforts; and made recommendations for improvement.

Final Report

To understand how the conditions identified in the Interim Report occurred and to evaluate additional allegations received during that inspection, the OIG team expanded its review to include these concerns:

- ***Risk of Harm****:* Whether patients were placed at risk for experiencing adverse clinical outcomes because of the Medical Center's inability to ensure that supplies and instruments reached clinical areas when and where they are needed.
- ***Service Deficiencies Affecting Patient Care***: Whether deficiencies in the Medical Center's services that manage the inventory, prepare medical instruments for use, procure prosthetic devices, and hire qualified personnel affected healthcare providers' ability to provide quality and timely services.
- ***Lack of Controls Over Assets***: Whether Medical Center practices put medical equipment and other assets of the federal government at risk for fraud, waste, or abuse.
- ***Failures in Leadership****:* Which leaders at the Medical Center, VISN 5, and VHACO effectively addressed Medical Center problems and unsafe conditions.

The OIG team conducted more than nine additional multiple-day site visits from April 10, 2017, through September 2017, with ongoing updates and follow-up activities. A multidisciplinary team of OIG healthcare inspectors, auditors, and criminal investigators conducted more than 100 interviews, including top leaders at the Medical Center, VISN 5, VHACO, and VA. Managers responsible for overseeing inventory and financial systems, logistics, prosthetics, sterile processing services, purchase card use, quality assurance, nursing, and many other departments and functions were questioned at relevant levels of the VA. Information was also sought from a wide range of personnel working in the Medical Center including clinical staff, technicians, service personnel, administrative and logistics staff, and detailees.

The OIG team reviewed hundreds of internal VA and VHA documents, multiple external consultant reports, and approximately 78,579 email messages and attachments. Analyses of

patient risk and adverse clinical outcomes were based on the professional judgment of OIG physicians and other healthcare providers who drew on accepted clinical practice and a review of the medical literature.

Part I: Risk of Harm

In addition to the interviews and document reviews already noted, OIG staff completed 124 independent case reviews as detailed in Table 2.

OIG staff focused their review of VHA and Medical Center Patient Safety Programs on whether required processes were comprehensive and functional, and whether executive-level committees provided appropriate oversight of quality and safety activities. OIG team members reviewed the following:

- All 2,674 EIRs entered and/or reported via WebSPOT[169] from January 1, 2014, through September 6, 2016. and analyzed the 376 EIRs that related to surgical instrument, equipment/reusable medical equipment, or sterile processing service issues
- Events reported through emails to the Patient Safety Manager from September 1, 2016, through February 6, 2017
- Events reported and closed in the Joint Patient Safety Reporting (JPSR) pilot system from February 6 through May 11, 2017
- Meeting minutes from relevant executive-level oversight committees from October 2015 through March 2017
- Root Cause Analyses (RCA) and the tracking of action items associated with the RCA
- VHA recall, national safety, and financial policy directives
- Medical Center reports of recalls and emails describing actions taken as a result of recall notices

The OIG team provided a copy of its analysis regarding the number of events not reported to the NCPS to the Medical Center Patient Safety Manager. The manager concurred with the OIG finding that 206 patient safety events were not reported to the NCPS.

[169] VHA Handbook 1050.01. WebSPOT is a software application used by medical facilities to report and document events in the VHA Patient Safety Information System.

Part II: Service Deficiencies Affecting Patient Care

To supplement interviews with relevant staff, the OIG conducted the following work.

Failures in Effective Inventory Management and Availability of Medical Supplies, Instruments, and Equipment

OIG staff analyzed transaction data and directly observed the process for ordering and receiving items using GIP. In addition, the team

- Spot-tested the accuracy of data in GIP by randomly selecting and physically counting the same 10 items located in the main clean storage area on three separate occasions over four months—each time comparing those physical counts to the recorded GIP data,
- Analyzed September 2016 and April 2017 purchase orders to determine if the Medical Center ordered items in excess of normal stock levels and physically counted those items in the on-site warehouse to quantify any excess, and
- Reviewed emails to identify specific supply shortages.

Except where otherwise indicated, the OIG team validated specific shortages identified through interviews, emails, and reports from GIP.

Clean/Sterile Storerooms

OIG staff physically inspected clean/sterile storerooms for medical supplies on three separate visits after the Interim Report was issued, reviewing 25–30 storage areas per inspection.[170] The clean/sterile storerooms were located in the bronchoscopy suite; cardiac catheterization and gastroenterology (GI) laboratories; dental, dermatology, eye, oncology, and pulmonary clinics; the dialysis unit; the ED, OR, and ambulatory surgery area; inpatient units (Progressive Care Unit, medicine, oncology, and telemetry) and intensive care units; primary and specialty care clinics; and SPS. During successive inspections, an OIG team returned to areas that were not in compliance with requirements for proper storage of medical supplies and added new areas for review based on information obtained through interviews.

[170] During the weeks of March 27 and April 3, 2017, OIG staff inspected 25 clean/sterile storerooms. During the post-Interim Report weeks of April 25 and June 26, 2017, the team inspected 29 and 30 (respectively) clean/sterile storerooms, and 27 areas during the week of August 29, 2017. During the first inspection OIG staff combined two rooms in the dialysis area as one, two rooms in the dental area as one, and during subsequent inspections, added the Same-Day Surgery area and a new storage area in the GI Lab.

In addition, OIG staff reviewed RME, Environment of Care (EOC), and Infection Control committee minutes and actions resulting from the Medical Center EOC inspections from FY 2016 and FY 2017 through June 30, 2017.

SPS Reprocessing of Reusable Medical Instruments and Equipment

OIG team members reviewed emails and issue briefs, and inspected the SPS department and satellite reprocessing areas, in addition to these activities:

- Checked for accessible written SOPs related to proper reprocessing, maintenance, and storage of RME
- Evaluated the completion of SPS staff competencies (both Medical Center and contract employees)
- Determined whether SOPs were appropriately updated and consistent with manufacturer's instructions
- Observed the cleaning of instruments within the SPS decontamination area to assess compliance with Medical Center SOPs and manufacturer's instructions
- Reviewed the Medical Center loaner instrumentation process to evaluate the management and reprocessing of loaned instrumentation and nonsterile nonbiological implantable devices received for specialty operative procedures
- Examined whether SPS managers were aware of and appropriately responded to reported EOC concerns in reprocessing areas
- Reviewed relevant directives, standards, guides, and reports[171]

In August and September 2017, OIG staff returned to the Medical Center and obtained documentation of progress made regarding updating SOPs and staff competencies.

To evaluate infection control issues, the OIG team reviewed VHA Infection Control and EOC directives, Joint Commission infection control and EOC standards, and other relevant documents. OIG health system specialists reviewed 174 surgical cases plus 28 scope procedures performed between February 28 and March 16, 2017. One surgical scope case and four surgical procedures with documentation of possible surgical site infections were reviewed further by an

[171] The reviewed documents included VHA directives, American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) standards, Association of Perioperative Registered Nurses (AORN) standards, The Association for Professionals in Infection Control and Epidemiology (APIC) standards, OIG Combined Assessment Program (CAP) Environment of Care review guides, Medical Center policies, RME and OR committees meeting minutes, and NPOSP reports.

OIG medical consultant. No surgical site infections were found to be associated with the SPS findings.

To address an allegation received during the inspection related to whether patients may have contracted Hepatitis C during a Medical Center procedure, OIG physicians conducted an EHR review. They identified all patients at the Medical Center who tested positive for Hepatitis C and then checked whether they had an OR-based procedure at the Medical Center in the *year preceding* their first positive Hepatitis C test. The OIG concluded that the evidence was not consistent with patients acquiring Hepatitis C in a Medical Center OR during the year studied.[172]

Open and Pending Prosthetic Consults

In addition to interviewing leaders and staff knowledgeable about prosthetics and purchasing, the OIG team retrieved a list of all open and pending prosthetic consults as of March 31, 2017, to assess their status and whether patients with selected types of consults experienced adverse clinical outcomes. OIG staff reviewed the EHRs of identified patients as described in the report. Because one veteran waited more than one year for a prosthetic limb, they reviewed the EHRs of other veterans with an open or pending consult for a prosthetic limb or appliance to determine whether the patients experienced a delay in receiving their devices, and if so, whether the patients experienced an adverse clinical outcome associated with the delay.

The OIG team also reviewed VHA and Medical Center policies, VHA Prosthetics Business Rules, the Medical Center Fiscal Service transaction/purchase numbering process, and other relevant documents.

Inadequate Staffing and HR Deficiencies

The HR review focused on current and past Medical Center HR operations and recruitment efforts. The OIG team interviewed current, former, and acting HR personnel; the Acting Associate Director of the Medical Center; and other Medical Center managers and staff with knowledge relevant to HR. The team also reviewed Medical Center staffing data and external reports discussing Logistics Service and SPS staffing deficiencies, including

- VHA and Medical Center HR policies, procedures, and directives;
- Calendar years 2015 and 2016 Resource Management Committee minutes;
- Issue briefs and reports to the VISN describing department vacancies, HR operations, and recruitment gaps; and

[172] OIG's examination revealed that 118 patients did not have an OR-based procedure in the year preceding the positive Hepatitis C test; 88 had evidence of Hepatitis C prior to surgery and no evidence of recurrence after a procedure in the OR; and eight patients had surgery more than 364 days before testing positive for Hepatitis C. (Most patients would have a positive test result within six months of exposure to Hepatitis C.)

- Authorized and actual staffing data, organizational charts, and documents that described filled and vacant positions for selected services from 2013 to 2017.

Part III: Lack of Control Over Assets

The OIG conducted a review of government purchase card use as well as financial and property management from April through July 2017. In addition to Logistics and Fiscal Service leaders, the OIG interviewed staff knowledgeable about the identified issues. The team also reviewed the following:

- Relevant VA Financial policies;[173] VHA Directive 1761, *Supply Chain Inventory Management* (October 2016); and memoranda from the Deputy Under Secretary for Health transmitted to VHA facilities that described Logistics Service staff purchase card responsibilities and appropriate practices
- Medical Center operating and spend plans, and data on supply and equipment expenditures
- Purchase card data for medical supplies and equipment from October 1, 2014, through April 3, 2017
- VA's Veterans Equitable Resource Allocation (VERA) for VISN 5 as it related to how the Medical Center receives its general purpose funds allocation

The team observed nonexpendable property and equipment stored in the Medical Center on-site and off-site warehouses and various other storage areas on the grounds. They also interviewed Medical Center staff to discuss the storage procedures of nonexpendable items and how excess inventory was managed.

Part IV: Failures in Leadership

The OIG review focused on selected Medical Center, VISN, and VACO leaders' roles and responsibilities in identifying, reporting, and correcting the deficiencies described in this report. Top VA, VHA, VISN, and Medical Center leaders were questioned (including some acting in key positions of authority and former officeholders) about their relevant duties and actions. The OIG also interviewed staff at multiple levels in VA—from services personnel in the Medical Center to program office personnel within VHA. The OIG team reviewed organizational charts, selected internal and external reports, emails, the Medical Center Director official personnel file, and the Office of Accountability and Review (OAR) findings related to the Medical Center

[173] Policies included VA Financial Policy, Volume XVI, Chapter 1, VA Financial Policies and Procedures, Quality Financial Information, Volume 1, and Office of Management and Budget (OMB): *Preparation, Submission, and Execution of the Budget*, OMB circular A-11, *Budget Justification Materials*, (July 2016).

Director's performance and conduct. OIG staff also reviewed documents related to the VISN 5 Logistics Service scorecard, issue briefs, VHA Program Office policies, and Findings Aggregation Categorization & Trending System and SAIL data relating to the Medical Center.

The OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's Quality Standards for Inspection and Evaluation.

Appendix B: Relevant Reports

Title/Author/Date	Review Topics and Findings/Results
Logistics Business Review VA Management Quality Assurance Service (MQAS) January 2013	• Nonexpendable personal property management • Expendable item management (GIP and PIP) • Inventory support/distribution support for primary and secondary areas • Storage and distribution *Summary Results*: Deficient conditions were found in all selected areas of the review, including nine repeat findings and two concerns related to compliance with VA and VHA directives.
Network External Review VISN 5 May 2013	• Nonexpendable inventory • Expendable inventory • Warehouse operations *Summary Results*: Deficient conditions identified included EIL management, excess equipment, use of GIP and its associated reports, stock levels, and cleanliness of sterile supply areas, among others.
Point of Use Assessment Report ShipCom (Catamaran Vendor) February 2014	• Point of Use program assessment to evaluate the supply chain performance with regards to medical supplies and to highlight improvement opportunities that exist to further enhance supply chain efficiency and effectiveness *Summary Results*: The auto-gen, barcodes, and scanned processes are not used anywhere. Logistics staff “are experiencing challenges with the manual replenishment process that is currently established.” The lack of handheld computer use and the lack of available resources were mentioned as main obstacles.

Title/Author/Date	Review Topics and Findings/Results
VISN 5 Supply Chain and Logistics—Final Assessment Deliverable Pricewaterhousecoopers November 2014	• Supply chain practices and performance of the VISN 5 enterprise and VAMCs *Summary Results*: The Washington DC VA Medical Center had a high variation in labor expense; led VISN 5 in purchase order spending; and accounted for 50 percent of all VISN 5 Logistics purchase order expenses.
VISN 5 Logistics—Program Update through July 31, 2015	• Follow Up to Pricewaterhousecoopers report • Prime vendor and supply spend analysis • Logistics staffing *Summary Results*: The Washington DC VA Medical Center expendable staff ceiling was low compared to peer stations (12 FTE ceiling vs. average 1a ceiling 35.9 FTE); the Medical Center had high vacancy rates under the current ceiling (33% in expendable and 50% in nonexpendable)
NPOSP Site Visit Report April 2015	• Evaluation of SPS operations and related areas performing decontamination, sterilization, high-level disinfection, and storage of RME *Summary Results*: Multiple deficiencies included SOPs, competencies, manufacturer's instruction for use, RME Master List, quality assurance checks, and sterile storage. The report identified 53 needed actions.
NPOSP Site Visit Report September 2015	• Continuation of the April 2015 NPOSP visit to evaluate ongoing responses and risk-mitigating actions underway within SPS *Summary Results*: There were 29 of 53 action items addressed and completed. NPOSP noted that the Medical Center needed to "re-open three action items that were previously closed. These include: adequate staffing, completion of RME minutes and weekly QA monitoring and checks for ultrasonic washer, washer disinfector and cart washer."
Governance Call Notes January 2016	• Discussion between VHA PLO and the vendor focusing on Catamaran implementation *Summary Results*: Catamaran is not routinely used; the Medical Center requested additional resources. The VA POU team expressed that they do not support this request as "the DC site has been supported and appear [*sic*] to be making no effort to use the system on their own"

Title/Author/Date	Review Topics and Findings/Results
Nursing Staffing and Supply Shortages VISN 5 QMO Review May 2016	• Nurse vacancies • Availability and functionality of support services (MSAs, HR, Logistics) • Functionality of equipment *Summary Results*: There were 98 nursing vacancies, "broken" supply chain HR processes, among others. A recommendation from VISN was to decrease medical/surgical beds by a minimum of 25–30.
NPOSP Site Visit Report November 2016	• Follow-up to the 2015 NPOSP visits *Summary Results*: New findings included, among other conditions, that deionized water used for washing and disinfecting should be plumbed; RME should be cleaned in accordance with manufacturer's instructions for use; and instrument PAR levels should be increased to meet demands. Repeat findings included deficiencies in SOPs, competency folders, and the currency/availability of manufacturers' instructions for use.

** This table includes formal reports and communications specific to the Washington DC VA Medical Center. In this report, the OIG also references two published reports that discuss more systemic supply chain inventory management issues within VA: (1) Mitre Corporation. Independent Assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs, September 1, 2015, and (2) Commission on Care. Final Report of the Commission on Care, June 30, 2016.*

Appendix C: Management Comments—Under Secretary for Health[174]

Department of Veterans Affairs

Memorandum

Date: FEB 15 2018

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Critical Deficiencies at the Washington, DC VA Medical Center (7876525)

To: Director, Rapid Response, Office of Inspector General (54RR)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Critical Deficiencies at the Washington, DC VA Medical Center (DC VAMC). On behalf of the senior leaders at DC VAMC, Veterans Integrated Service Network (VISN) 5 and the Veterans Health Administration (VHA), we concur with OIG's findings and recommendations and provide the attached action plans.

2. At the time of the Inspector General's Interim Report, the Secretary and former Acting Under Secretary for Health took immediate actions to replace DC VAMC leadership and amplify VISN 5's efforts to fill vacancies in logistics and sterile processing service. Senior leadership immediately visited the DC VAMC to assess the situation and launch rapid interventions and corrective actions.

3. During the intervening 11 months, VHA, VISN 5 and DC VAMC made substantial progress on the concerns raised by the Inspector General in the Interim Report. We've also been taking actions on concerns as they have surfaced during our improvement efforts. Below we highlight a few of the important actions and progress:

   a. Established the Incident Command Center (ICC) at the DC VAMC: the ICC implemented a robust oversight process that identified and promptly addressed new supply or equipment shortages. The ICC instituted a 24-hour hotline for ordering urgent and emergent medical supplies.

   b. Assured all patients were safe and none were harmed: VHA's National Center for Patient Safety launched a rapid-response approach with onsite visits, bi-weekly and weekly calls with the facility and VISN and ensured all patient safety issues were appropriately addressed. As of January 31, 2018, the facility has cleared their backlog of patient safety incident reports.

   c. Awarded contract to construct a 14,200 square foot space for Sterile Processing Services. The $8.9 million project will be completed in March 2019. More than $3.1 million in surgical instruments have been purchased to ensure an appropriate inventory based on the needs of the Veterans served and our surgical teams.

[174] The recommendations for the Under Secretary for Health (USH) were submitted to the Executive in Charge who has the authority to perform the functions and duties of the USH.

d. Transitioned inventory to the General Inventory Package: Medical Surgical Primary Inventory has been entered in the system and the periodic automatic replenishment levels are being validated to ensure stock outages do not occur.

e. Secured the off-site warehouse to restrict access and protect medical equipment and supplies.

f. Eliminated all pending prosthetics consults greater than 30 days, more than 9,000 to zero.

g. Ensured ordering of prosthetics is not interrupted by end-of-fiscal-year financial transitions: At the end of fiscal year 2017, there was no disruption of prosthetic ordering due to lack of funds.

h. Allocated resources and expedited hiring into Logistics, Sterile Processing Service vacancies: A year ago, Logistics Service at the DC VAMC was 59 percent understaffed. Today, 54 staff have been hired; 7 positions remain under recruitment. To mitigate the staffing shortage, the DC VAMC has a total of 14 Contract Logistics staff on board. The Sterile Processing Service currently has 12 Sterile Processing Service staff vacancies, 8 of which are currently filled with contract staff; two additional contract staff are slated to come onboard.

4. We are all grateful to the staff at the DC VAMC who demonstrated strength, creativity and commitment to ensure that Veterans were safe during this difficult time. On behalf of the VHA leadership teams involved in this effort, we appreciate the OIG's recognition of their work in the body of this draft report. We encourage all employees to speak up and raise concerns to leadership. They are an integral part of our front-line safety net and we take their concerns seriously.

5. As we move forward, we are putting in place a reliable pathway for all facilities, VISNs and business lines to escalate high-priority concerns to senior leadership for prompt action and follow-up. This is woven into our on-going modernization efforts. I am dedicated to continued and sustained improvement and incorporating lessons learned across our network.

6. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

Carolyn M. Clancy, M.D.

Attachment

Responses to OIG Recommendations

The following Under Secretary for Health's comments are submitted in response to the recommendations in the OIG report:

Recommendation 4. The Under Secretary for Health specifies criteria under which individual medical centers will conduct wild card Aggregated Reviews for high-frequency patient safety events.

VHA Executive in Charge Comments: Concur

The National Center for Patient Safety (NCPS), in response to this recommendation, has clarified that each facility must conduct a wild card Aggregated Review during fiscal year (FY) 2018 for patient safety events with a safety assessment code (SAC) score of 1 or 2 involving the "availability of supplies, devices, instruments, or equipment." A facility Aggregated Review or a Root Cause Analysis performed within the previous 12 months for this event type can be used to fulfill the requirement.

For FY 2019 and beyond, all facilities are required to conduct a wild card Aggregated Review for patient safety events with a SAC score of 1 or 2 that represent either the most often reported type of event (using the Joint Patient Safety Report "event subtype", "event details", or "location" fields to count/sort) or a type of event that is trending upward in report frequency. This wild card event type cannot be one of the already required Aggregated Review event types (falls, missing patients, adverse drug events). In all instances, these wild card Aggregated Reviews count towards the minimum number of eight Root Cause Analyses or Aggregated Reviews for the given year.

NCPS will regularly report items identified in the Aggregated Reviews to facilities and Veterans Integrated Service Networks (VISN) to facilitate improved practices enterprise wide. Additionally NCPS will provide direct feedback to facilities on their Aggregated Reviews.

Oversight of this recommendation will occur through the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when facilities have conducted requisite wild card Aggregated Reviews for FY 2018 and NCPS demonstrates evidence of effective communications with facilities and VISNs on the results of wild card Aggregated Reviews.

Status	Target Completion Date
In progress	September 2018

Recommendation 33. The Deputy Under Secretary for Health for Operations and Management[175] ensures that the Veterans Health Administration Procurement and Logistics Office conducts regular audits of the logistics services within Veterans Health Administration

[175] Per correspondence with VHA, recommendations regarding program offices fall under the authority of the USH. Since the DUSHOM reports directly to the USH, Dr. Clancy's concurrence memorandum covers this recommendation and the DUSHOM's response.

medical centers to assess compliance with VA and Veterans Health Administration policies pertaining to procurement and logistics, and makes certain that timely and effective remediation occurs in response to all noncompliant conditions identified as a result of those audits.

VHA Deputy Under Secretary for Health for Operations and Management Comments: Concur

VHA's Procurement and Logistics Office [P&LO] will continue to coordinate and conduct regularly scheduled logistics audits and unannounced audits at selected VHA Medical Centers, as needed. VHA P&LO will conduct regular oversight of audit findings and recommendations generated from any Logistics reviews/audits performed at VHA Medical Centers. Evidence that logistics audits have been regularly conducted and effective remediation in response to recommendations has occurred will be followed through the integrated oversight process outlined in recommendation 40. VHA will have completed a full year of monitoring by March 2018, and will continue audits and following up through the end of fiscal year 2018.

Status	Target Completion Date
In progress	September 2018

Recommendation 36. The Under Secretary for Health clearly defines program offices' responsibility for reporting high-priority recommendations to responsible individuals within Veterans Health Administration Central Office, and requires independent verification that the relevant medical center and/or Veterans Integrated Service Network have implemented the recommendations.

VHA Executive in Charge Comments: Concur

VHA must ensure that business lines have a reliable pathway for escalating high-priority concerns to senior leadership for prompt action and follow-up.

The Office of the Deputy Under Secretary for Health for Operations and Management [DUSHOM] will collaborate with relevant program offices and stakeholders to develop a fast-track escalation process for issues that affect VISN or facility operations. Issues include, at minimum, national program office concerns supported by data or findings, high priority recommendations, recommendations from oversight bodies, and concerns raised directly by VISNs or facilities. The process will include a rapid, initial review to confirm the scope and urgency of the concern. The process will establish criteria for fast-track issues, clarify program office responsibilities for using fast-track process, establish procedures for managing fast-track concerns, and establish standards for follow-up and independent assurance of resolution.

Status	Target Completion Date
In progress	April 2018

Recommendation 37. The Under Secretary for Health develops a means of aggregating and analyzing available data on Logistics, Sterile Processing, Prosthetics, and Human Resources services (or other services as the Under Secretary for Health deems appropriate) so that major

operational deficiencies at a medical center or Veterans Integrated Service Network that affect multiple services or functions may be detected and corrected.

VHA Executive in Charge Comments: Concur

This recommendation reinforces key Agency modernization efforts. The Secretary for Veterans Affairs and the Executive in Charge for VHA are committed to removing unnecessary bureaucratic layers, breaking down barriers between service lines, and integrating information horizontally across the enterprise.

Importantly, to develop a reliable means for aggregating and evaluating data across services will likely require many years to develop, test, validate, and fully implement because it is complex and highly dependent on data that may not currently exist. These efforts may extend to our Department partners who can provide important direction and input into our analysis.

On November 30, 2017, Reporting, Analytics, Performance, Improvement and Deployment (RAPID) briefed the Assistant Deputy Under Secretary for Health for Administrative Operations to begin planning a pilot study to determine the ability to centrally monitor administrative services where a facility is experiencing challenges. Milestones and requirements for this new capability are in the process of being established, and additional statistical analysis will be conducted to determine if the measures are reliable, valid, and responsive to change. If so, RAPID will create a visual tracking system. RAPID is reliant on program offices development of metrics/measures in order to construct the interface so there are a number of interdependencies that need to be addressed. If this pilot is successful, then a full application will be deployed.

Status	Target Completion Date
In progress	September 2019

Recommendation 38. The Under Secretary for Health takes appropriate administrative action to address the conditions identified in this report.

VHA Executive in Charge Comments: Concur

The Secretary for Veterans Affairs and the former Acting Under Secretary for Health directed removal of the DC VAMC director upon learning of leadership decisions that put Veterans at risk. Additionally, VHA has taken appropriate administrative actions against other responsible leaders.

To ensure all necessary administrative personnel actions are handled to completion, VHA's Workforce Management and Consulting (WMC) Office will monitor progress on proposed and approved administrative personnel actions found necessary to address the conditions in this report. WMC will report progress on administrative actions to the Under Secretary for Health as required by the oversight process described in recommendation 40, and per the Office of Inspector General (OIG) status update requirements every 90 days. WMC will provide consultation to the Office of Accountability and Whistleblower Protection and the Deputy Under Secretary for Operations and Management as needed on policy for employees covered under Title 38 and Title 38 Hybrid hiring authorities.

Status	Target Completion Date
In progress	Depends on completion of administrative personnel actions

Recommendation 40. The Under Secretary for Health verifies the successful implementation of all recommendations contained within this report.

VHA Executive in Charge Comments: Concur

VHA's Management Review Service will collaborate with relevant national, VISN, and facility program officials, to develop a vertically and horizontally integrated oversight process for ensuring all of the recommendations contained within this report are successfully implemented and sustained to the satisfaction of the Under Secretary for Health. The oversight process will adhere to OIG's required status updates every 90 days. It will require appropriate monitoring, auditing (both announced and unannounced) and reporting at all three levels of the organization: facility operations, VISN oversight, national program office oversight, and independent assurance. Successful implementation means sufficient evidence demonstrates durable, sustained resolution of the intent of the recommendation. The oversight process will be written and presented to VHA leadership by March 30, 2018. Completion of this recommendation will occur when OIG has closed all of the recommendations and the Under Secretary for Health is satisfied with the status of facility performance, VISN oversight, and national program office oversight.

Status	Target Completion Date
In progress	Dependent on closure of the recommendations

Appendix D: Management Comments—VISN Director

Department of Veterans Affairs **Memorandum**

Date: FEB 0 9 2018

From: Director, VA Capitol Health Care Network (10N5)

Subj: Healthcare Inspection — Critical Deficiencies at the Washington DC VA Medical Center

To: Director, Rapid Response

1. I have reviewed and concur with the findings and recommendations in the OIG report entitled, Healthcare Inspection— Critical Deficiencies at the Washington DC VA Medical Center.

2. Should you require additional information, please contact Quality Management Officer, VA Capitol Health Care Network, VISN 5, at 954-541-7514.

Joseph A. Williams, Jr.

Attachment

Responses to OIG Recommendations

The following VISN Director's comments are submitted in response to the recommendations in the OIG report:

Recommendation 16. The Veterans Integrated Service Network 5 Director secures adequate space and funding for the Washington DC VA Medical Center satellite reprocessing areas, which includes separate decontamination, processing, and packaging areas in accordance with Veterans Health Administration Sterile Processing Service policies.

VISN 5 Director Comments: Concur

The VISN has secured space and funding through an $8.9 million Non-Recurring Maintenance Project for construction that was awarded September 25, 2017. The project was awarded in accordance with National Program Office of Sterile Processing recommended best practices to centralize Sterile Processing Service operations by reducing or eliminating satellite reprocessing locations. The project completion is targeted for March 2019.

This construction project provides space for high level disinfection in Sterile Processing Service for all 'satellite' reprocessing locations (e.g., gastrointestinal endoscopy, ear, nose, and throat endoscopy) to be permanently relocated to Sterile Processing Service, except for Immediate Use Sterilization reprocessing that is done in the Operating Room. Centralized reprocessing of all reusable medical equipment allows Sterile Processing Service to conduct more robust oversight (including competencies, workflow, environmental requirements, quality assurance, staffing, and work assignments).

Status	Target Completion Date
In progress	March 2019

Recommendation 17. The Veterans Integrated Service Network 5 Director makes certain that the Washington DC VA Medical Center Director resolves open and pending prosthetic consults and implements a plan to address future prosthetic consults in accordance with Veterans Health Administration policy.

VISN 5 Director Comments: Concur

In April 2017, it was identified that the DC VAMC had more than 9,000 consults over 30 days old and approximately 12,000 consults in total. VISN 5 and DC VAMC leadership established an action plan to resolve the open and pending prosthetics consults. As of January 2018, DC VAMC has no pending prosthetics consults over 30 days and the average days to complete prosthetics consults is 2.1 days.

The action plan to reduce consults and improve access to care includes:

1. A staffing assessment for consult backlog management was conducted in April 2017 which resulted in: a detail assignment for Acting Chief of Prosthetics; establishment of a remote consult processing team; and clinical nursing support.

- Leadership ensured timely hiring of additional front-line staff, to include six purchasing agents, one inventory technician, and two clerks. The permanent Chief of Prosthetics has been hired and will start April 2018.

2. Leadership implemented a daily Prosthetics consults dashboard to review data and weekly meetings to communicate consult reduction to leadership. The Prosthetics consult dashboard process improvement tool is used to assess consult volume, identify VISN-wide trends, and adjust workflow to sustain successes.

- Identified consult categories and implemented new consult template(s) to streamline the identification of patient requests and improve work flow and timeliness.
- Established newly awarded Durable Medical Equipment and Orthotics contracts and worked with National Contracting Office to complete vendor payments for outstanding invoices and close open orders that had been delivered.

3. Leadership facilitated Purchase Cards, Consults, and Prosthetics Management Refresher Trainings to Prosthetics' staff, resulting in improved program awareness and the ability to manage consults more effectively to increase access to care and sustain improvements.

- VISN Financial Quality Assurance Manager and Purchase Card Coordinator will complete quarterly purchasing audits and the VISN Compliance Officer will conduct quarterly facility consult management reviews.

4. A Programmatic Prosthetics site review was conducted by the VISN 5 Prosthetics program manager, resulting in ongoing updated action plans. Plans include improvement initiatives, responsible individuals, target completion dates, and monitors for sustainability.

- The VISN will ensure future prosthetic consults are in accordance with VHA policy through ongoing Prosthetic Site reviews, data monitoring, and monthly progress updates from the facility.

VHA will oversee VISN oversight of this recommendation through the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when the facility demonstrates the appropriate management of pending prosthetics consults and the VISN demonstrates evidence of regular monitoring of the facility's performance.

Status	Target Completion Date
In progress	June 2018

Recommendation 19. The Veterans Integrated Service Network 5 Director, together with Washington DC VA Medical Center leaders, develops a staffing plan to fill vacancies that includes accurate numbers of authorized positions by service that is based on clinical and administrative workload and other appropriate measures, and includes contingencies for staffing areas with high attrition rates.

VISN 5 Director Comments: Concur

To prevent future staffing deficiencies medical center-wide, VISN and facility leaders will develop a data based staffing plan to fill vacancies that includes accurate numbers of authorized

positions by service, that is based on clinical and administrative workload and other appropriate measures, and that includes contingencies for staffing areas with high attrition rates.

VHA will consider this recommendation resolved when the Deputy Under Secretary for Health for Operations and Management approves the proposed staffing plan.

Status	Target Completion Date
In progress	September 2018

Recommendation 20. The Veterans Integrated Service Network 5 Director ensures the timely completion of hiring actions at the Washington DC VA Medical Center until staffing deficiencies in Logistics Service and Sterile Processing Services are fully resolved.

VISN 5 Director Comments: Concur

The VISN and facility Directors will meet monthly to review hiring for Logistics Service and Sterile Processing Services until staffing is sufficient to demonstrate effective operations.

Staffing deficiencies in logistics and Sterile Processing Service significantly contributed to operational weaknesses at the DC VAMC. Importantly, the Secretary, former Acting USH, VISN and facility directors took prompt actions to recruit and hire needed staff. A year ago, Logistics Service at the Washington DC VAMC was 59 percent understaffed. Today, 54 staff have been hired; 7 positions remain under recruitment. To mitigate the staffing shortage, the DC VAMC has a total of 14 Contract Logistics staff on board. The Sterile Processing Service currently has 12 Sterile Processing Service staff vacancies, 8 of which are currently filled with contract staff; two additional contract staff are slated to come onboard. The DC VAMC plans to fill vacant positions by using all recruitment flexibilities to include non-competitive appointments, when applicable. To prevent future staffing deficiencies in these critical operational areas, the staffing plan described in recommendation 19 will include contingency plans for filling vacancies in high attrition areas.

VHA will oversee VISN oversight of facility hiring through the integrated oversight plan described in recommendation 40.

Status	Target Completion Date
In progress	June 2018

Recommendation 25. The Veterans Integrated Service Network 5 Director ensures that the Washington DC VA Medical Center updates and maintains the Equipment Inventory List as required by VA policy and makes certain that the Washington DC VA Medical Center Director and Chief Logistics Officer are held accountable for the timely and accurate reporting of the Washington DC VA Medical Center Equipment Inventory List.

VISN 5 Director Comments: Concur

The VISN has a four-point oversight structure for holding the facility accountable to update and maintain the Equipment Inventory List:

1. The VISN Chief Logistics Officer will audit the facility Equipment Inventory List quarterly. The audit is conducted through a scheduled Quality Control Review, which includes random spot checks for accuracy, and required quarterly Equipment Inventory List reports.
2. The VISN Chief Logistics Officer provided a 13-month planning worksheet for tracking the facility's Equipment Inventory List. The facility is required to complete this worksheet and submit for VISN review each month.
3. The VISN Chief Logistics Officer trained facility staff and will provide training bi-weekly to ensure they can perform their responsibilities for managing equipment inventories.
4. The VISN is developing an electronic tracking mechanism to facilitate tracking of the facility's monthly and quarterly reporting.

VHA will evaluate implementation of VISN oversight through the integrated oversight plan described in recommendation 40. VHA will consider this recommendation complete when the facility Equipment Inventory List has been updated and maintained for a full year and the VISN provides evidence of effective and timely monthly and quarterly oversight.

Status	Target Completion Date
In progress	March 2019

Recommendation 32. The Veterans Integrated Service Network 5 Director audits a representative sample of FY 2017 Washington DC VA Medical Center supply, instrument, and equipment purchases and ensures adequate internal controls for future purchases are in place.

VISN 5 Director Comments: Concur

VISN 5 leadership will audit a representative sample of fiscal year 2017 DC VAMC supply, instrument, and equipment purchases, and ensure internal controls are in place for future purchases. The VISN Chief Logistics Officer will ensure that future supply purchases are reviewed and executed according to recommended Periodic Automatic Replenishment levels established within the Generic Inventory Program and endurance levels defined by VHA Instruction 1761.1.

VHA will follow up on implementation of this recommendation through the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete upon review of the audit results and evidence that the VISN can ensure internal controls are in place for future purchases.

Status	Target Completion Date
In progress	June 2018

Recommendation 34. The Veterans Integrated Service Network 5 Director evaluates the accuracy of representations made by Washington DC VA Medical Center staff in connection with the completion of action plans arising out of the National Program Office of Sterile Processing October 2016 site visit and determines whether administrative actions should be taken as a result of those representations.

VISN 5 Director Comments: Concur

The VISN Director completed evaluation of the accuracy of representations made by DC VAMC staff in connection with the completion of action plans arising out of the National Program Office of Sterile Processing (NPOSP) October 2016 site visit. To date, the VISN Director currently has no evidence of misrepresentation of information in Sterile Processing Service action plans; however, if it is determined that misrepresentations were made, leadership will further investigate to determine if administrative action(s) are warranted.

VISN 5 leaders reviewed the status of the action plan arising from the NPOSP October 2016 site visit during a VISN-led inspection in April 2017, and recommended reopening several action items that had been designated as closed. The action items were reopened because there were instances in which staff lacked a clear understanding of the required actions, staff was unable to locate requested documents pertaining to the actions, and some actions identified as "future actions" had been prematurely closed. The Sterile Processing Service Chief who prematurely closed these action items transferred to another VA facility a few weeks prior to the VISN inspection. Since the April 2017 VISN inspection, the facility has submitted regular action plan updates that are reviewed by VISN and NPOSP leaders, and VISN and NPOSP leaders have conducted several on-site assist visits to help ensure accomplishment of outstanding actions. Note DC VAMC has assigned staff outside of Sterile Processing Service to independently verify and confirm completion and sustainment of all closed actions on the action plan. VISN leaders will also verify and confirm the accuracy of closed and open action items during the next VISN-led inspection, scheduled for April 2018.

VHA will follow up on this recommendation through the integrated oversight plan described in recommendation 40. VHA will consider this recommendation complete when the VISN reports findings from its evaluation to the Deputy Under Secretary for Health for Operations and Management.

Status	Target Completion Date
In progress	April 2018

Recommendation 35. The Veterans Integrated Service Network 5 Director institutes procedures designed to ensure the accuracy of future representations made by Washington DC VA Medical Center staff in connection with action plans submitted to oversight bodies such as Veterans Health Administration program offices.

VISN 5 Director Comments: Concur

VISN 5 is developing official network procedures that establish the process for VISN auditing of facility reports to oversight bodies. These procedures will establish VISN and facility responsibilities for accurately reporting status on corrective actions relative to any review or recommendation by an oversight body. The network procedures will apply to all facilities in VISN 5, one of which is the DC VAMC. The procedures will specify administrative actions that will result from misrepresentation to an oversight body.

VHA will consider this recommendation complete when the VISN receives approval from the Deputy Under Secretary for Health for Operations and Management, publishes the procedures,

informs all facilities in the VISN, and demonstrates auditing of facility reporting to oversight bodies. VHA expects completion of the procedures and sufficient evidence of VISN audits will require at least 1 full year.

Status	Target Completion Date
In progress	March 2019

Recommendation 39. The Veterans Integrated Service Network 5 Director oversees implementation of recommendations directed to the Washington DC VA Medical Center Director.

VISN 5 Director Comments: Concur

In alignment with recommendation 40, the VISN will collaborate with VHA's Management Review Service, and relevant national and facility program officials, to develop a vertically integrated oversight process for ensuring all of the recommendations contained within this report are successfully implemented to the satisfaction of the Under Secretary for Health. The oversight process will adhere to OIG's required status updates every 90 days. It will require appropriate monitoring, auditing, and reporting at all three levels of the organization: facility operations, VISN oversight, national program office oversight, and independent assurance. Successful implementation means sufficient evidence demonstrates durable, sustained resolution of the intent of the recommendation. The oversight process will be written and presented to VHA leadership by March 30, 2018. Completion of this recommendation will occur when OIG has closed all of the recommendations and the Under Secretary for Health is satisfied with the status of facility performance, VISN oversight, and national program office oversight.

Status	Target Completion Date
In progress	Dependent on closure of the recommendations

Appendix E: Management Comments—Medical Center Director

Department of Veterans Affairs **Memorandum**

Date: FEB 09 2018

From: Acting Medical Center Director, Washington DC VA Medical Center (688/00)

Subj: Healthcare Inspection— Critical Deficiencies at the Washington DC VA Medical Center

To: Director, VISN 5 VA Capitol Health Care Network (10N5)

1. I have reviewed and concur with the findings and recommendations in the OIG report entitled Healthcare Inspections - Critical Deficiences at the Washington DC VA Medical Center.

2. Please contact Acting Medical Center Director at the Washington DC VA Medical Center at 202-745-8350.

Lawrence B. Connell
Acting Medical Center Director

Responses to OIG Recommendations

The following Medical Center Director's comments are submitted in response to the recommendations in the OIG report:

Recommendation 1. The Washington DC VA Medical Center Director ensures that necessary supplies, instruments, and equipment are available in patient care areas at the Medical Center when and where they are needed.

DC VAMC Acting Director Comments: Concur

The following actions will be ongoing, indefinitely, to ensure that necessary supplies, instruments, and equipment are available in patient care areas at the medical center when and where they are needed:

Systems Utilization: As of December 31, 2017, the Central Supply Primary was made scannable as part of continuous quality improvement. The continued implementation of scanning capacity in the Central Supply Primary is being revalidated. Work is ongoing to validate periodic automatic replenishment (PAR) levels to ensure stock outages do not occur. Secondary inventory points are being set up for auto-generation (to be completed no later than June 30, 2018). For equipment, a process review was conducted and assets are now being entered into Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) upon receipt. To prevent disruption of daily operations, assets not currently in the system will be entered into AEMS/MERS during off-hours. All assets will be entered into AEMS/MERS no later than September 30, 2018.

Rounding Program: The Deputy Logistics Chief and Expendable Inventory Supervisor conduct weekly rounds to visually inspect secondary inventory points and speak to customers about inventory support received from Logistics Service. DC VAMC will maintain an accurate list of secondary inventory points that includes, at a minimum, the location and the Inventory Managers and Supply Technicians assigned to each location.

Operating Room Huddles: Logistics Service has and will continue to participate in daily Operating Room (OR) huddles to ensure urgent supply requirements are addressed expediently.

PAR Level Reviews: Inventory Manager has and will continue to conduct regular reviews of PAR levels with clinical customers to ensure ongoing requirements are addressed. Review schedules will be discussed with and agreed to by the supported clinical service.

Medical Center Governance Structure:

1. The Clinical Product Review Committee (CPRC) has been re-engaged and is responsible for ensuring supplies and instrumentation are approved for use in the Washington DC VA Medical Center (DC VAMC).

2. The Equipment Committee has been re-engaged and is responsible for ensuring equipment is approved for use in the DC VAMC.

3. The Reusable Medical Equipment Committee has been re-engaged and is responsible for governance over the use of reusable medical equipment in the DC VAMC.

These ongoing actions build on the following emergent actions taken upon receipt of the findings of the interim report:

As the conditions and findings noted in this report began surfacing, the VISN 5 Network Director stood up an Area-wide Command Center (ACC) and directed the DC VAMC to stand up a local Incident Command Center (ICC) comprised of subject matter experts within the Veterans Health Administration (VHA) to streamline medical supplies and logistics service processes, address staffing needs, and assess the overall environment of care. The ICC implemented a robust oversight process that identified and promptly addressed new supply or equipment shortages, including a 24-hour hotline to provide a direct line of communication to order urgent and emergent medical supplies for all areas of the DC VAMC and corresponding CBOCs. This oversight process also included daily supply rounds to all patient areas by logistics and nursing staff, multidisciplinary Operating Room huddles [including Logistics, Sterile Processing Service, Prosthetics, Nursing and Pharmacy], and timely review and action on issues brought forth to the ICC.

On April 14, 2017, the DC VAMC began the process of transitioning to the Generic Inventory Package (GIP). This transition involved cataloguing the following Inventory points: Medical Surgical Primary; on-site and off-site warehouses; critical secondary inventory locations (ICU's, ED, OR, Dialysis, and Cath Lab); and non-critical primary and secondary sites. Once inventoried, the items were entered into the GIP. VISN 5 Chief Logistics Officer and a member of his staff arrived at the DC VAMC March 2017, to assist in the inventory, cataloguing and rebuilding of the computer software inventory system. To implement an effective inventory management system throughout the DC VAMC, the acting Under Secretary for Health (USH) deployed logistics experts to the medical center from the VHA Procurement & Logistics Office, VISN 5 and other VA facilities to stand up and rebuild the Generic Inventory Package (GIP) which is the authorized software program used by VA medical facilities for management of medical supplies as well as implement inventory management best practices in supply and equipment management.

As part of this process, DC VAMC ordered a 90-day supply of projected medical and surgical needs. By June 5, 2017, the immediate actions taken ensured necessary supplies and equipment were available at the patient care area at DC VAMC. As a result, the medical center transitioned out of emergent status into sustainable normal processing of procurement actions, with Logistics Service receiving calls for supplies during the day-time hours, and the Nursing Supervisor receiving urgent/emergent calls for supplies during off-hours. The acting Associate Director continued to hold ICC meetings once daily until September 30, 2017, to ensure that supply needs were met within the facility.

Oversight of the facility's successful transition to an accurate Generic Inventory Package with a mature automatic replenishment function will be conducted by the VISN and Central Office over the upcoming year. VHA will consider this recommendation complete when audits of the facility's Generic Inventory Package demonstrate consistent accuracy over time, and review of VISN oversight demonstrates regular monitoring of the site's progress, including appropriate interventions to clear any barriers the site may encounter.

Status	Target Completion Date
In progress	September 2018

Recommendation 2. The Washington DC VA Medical Center Director requires operating room staff to conduct the final validation that all supplies, instruments, and equipment needed to perform the planned procedure and to address potential complications are in the operating room and available for use.

DC VAMC Acting Director Comments: Concur

Following the interim OIG report, the acting Medical Center Director directed OR staff to conduct daily 5-day look-ahead huddles to assure that supplies, instruments and equipment that are needed to perform the planned procedure are available for use. The daily huddles consist of OR nursing, anesthesia, Sterile Processing Service and Logistics staff. Each day, a review of current day cases is conducted to identify any systems issues that occurred with respect to supplies, instruments and equipment. Then the next day's cases are reviewed to assure that the needed instrument trays, supplies and equipment will be available. In the case of implants, a chart review is conducted to assure that appropriate procurement procedures have been followed (for example, a pre-implant consult). In the case of loaner trays, Sterile Processing Service is available to verify that the trays have arrived and are processed in time for the scheduled procedure. Once all procedures have been reviewed for the following day, scheduled procedures are reviewed for the following 4 days.

There is a daily OR report to leadership during morning report where any issues that occurred the day before in the OR with respect to supplies, instruments or equipment availability are reviewed. This enables immediate action planning to address any such issues identified. Through this robust daily huddle monitoring, OR staff have identified the need to conduct instrument tray reviews, and to re-establish a system of peel-pack instruments in the OR Clean Core for common use instruments. OR staff implemented performance improvement plan to conduct the tray reviews that will be completed by April 1, 2018. The tray review will identify missing instruments that will be promptly ordered. The second step, implementation of peel pack instruments, will be implemented by May 1, 2018. The daily huddle will assess effectiveness of these systems level corrective actions, and refine processes to ensure equipment, instruments, and supplies are available for scheduled procedures.

Oversight of the facility's successful resolution to ineffective management of supplies, instruments and equipment in the OR will be monitored at the VISN and headquarters. VHA will consider this recommendation complete when:

1. The site demonstrates robust identification and effective resolution of process failures over the upcoming year; and
2. The VISN demonstrates oversight of the facility's process and evidence of appropriate intervention to ensure the facility sustains effective OR processes for managing supplies, instruments, and equipment.

Status	Target Completion Date
In progress	March 2019

Recommendation 3. The Washington DC VA Medical Center Director makes certain that the operating room staff have accurate lists of surgical instruments needed for particular procedures.

DC VAMC Acting Director Comments: Concur

VISN 5 leaders and the DC VAMC staff took the following steps to address this recommendation:

- In August 2017, the Case Cart lists associated with each surgical procedure were reviewed, updated, and verified by the OR nursing staff and the surgeons who perform those procedures. The lists are maintained on a shared computer drive so that all Operating Room staff members have access. Case Cart lists identify the instrument trays, associated disposable supplies, and equipment necessary to perform the procedure. The facility also implemented a Case Cart quality assurance process to identify and correct system level gaps going forward.
- In December 2017, the facility developed a primary inventory list of all surgical and clinic trays for the Sterile Processing Service. The primary list includes photographs of each completed tray and an inventory sheet is completed that identifies missing instruments for replacement, and details for managing supplies, instruments, trays, and equipment. Each surgical department is expected to, in collaboration with Sterile Processing Service, update and reconcile the count sheets for surgical instrumentation trays. Full implementation of this process is expected by April 1, 2018.
- As of December 31, 2017, DC VAMC secured a contract for the VenSero System which supports electronic inventory of loaner or vendor trays, tracking of surgical trays from vendors, and vendor coordination.
- DC VAMC is currently in the process of contracting for the use of CensiTrac which supports electronic inventory of surgical trays, instrument utilization, ease of communication, and improved accuracy and efficiency of sterile processing. The anticipated implementation date is August 1, 2018.

Oversight of the facility's implementation of the CensiTrac system will be conducted through the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when the facility demonstrates that OR staff have maintained accurate lists of instruments for surgical procedures for a full year after CensiTrac is in place.

Status	Target Completion Date
In progress	August 2019

Recommendation 5. The Washington DC VA Medical Center Director ensures that routine audits of incident reporting system entries are completed to ascertain that all patient safety events are in the National Center for Patient Safety database as required by Veterans Health Administration policy.

DC VAMC Acting Director Comments: Concur

Following the preliminary OIG report, published in 2017, the facility reviewed all incident reports in the Joint Patient Safety Reporting (JPSR) System to assure the SAC score was recorded and incidents were also entered into the NCPS data base (known as "SPOT."). The review found some incident reports had not been entered in SPOT and there was a backlog of

incident reports that had not been entered into either electronic reporting system. Processes were put in place to ensure the disposition of all JPSR patient event reports within 7 days and work on the backlog of pending reports that had not been entered into SPOT.

By the end of fiscal year 2017, timely closeout of events (including backlog from March 2017) was at 96 percent, improved from a baseline of 25 percent in July 2017. As of January 31 2018, 100 percent of the JPSR reports from the prior 12 months have been dispositioned.

The DC VAMC will continue audits to assure that patient safety events and near misses reported by staff in the JPSR data base are reviewed daily by Patient Safety staff with appropriate follow-up and referral for analyses within 7 days. The VISN will continue to report the percentage of reports dispositioned on the VISN Patient Safety Dashboard during fiscal year 2018. The Quality, Safety, Value Executive Council provides oversight of the facility patient safety program.

VHA will oversee implementation of this recommendation through the integrated oversight process described in recommendation 40. VHA will consider actions complete when the National Center for Patient Safety validates facility and VISN audit findings on entry of patient safety incidents in the appropriate databases and ensure completeness and consistency over time and completeness. VHA expects completion of this recommendation to require a full year of auditing.

Status	Target Completion Date
In progress	December 2018

Recommendation 6. The Washington DC VA Medical Center Director requires Medical Center oversight committees to follow up and initiate action as necessary on quality assurance matters related to supplies, instruments, or equipment.

DC VAMC Acting Director Comments: Concur

The DC VAMC has re-established the Clinical Product Review Committee and the Equipment Committee and charged them with responsibility for oversight on quality assurance matters related to supplies and equipment. Both committees will meet monthly and report to the Resource & Operations Executive Council. The Reusable Medical Equipment Committee is charged with oversight of reusable medical equipment and reports to the Nurse Executive Council. The three committees together are charged with identifying quality assurance matters, reporting them to leadership, directing appropriate corrective actions and following up on resolution of issues that affect supplies, instruments, or equipment. The two oversight councils report to the facility Executive Leadership Board.

VHA and the VISN will oversee effectiveness of this new facility governance structure through the integrated oversight process described in recommendation 40. VHA will consider actions on this recommendation complete when the three committees, the two councils, and the facility Executive Leadership Board demonstrate effective governance of quality assurance matters related to supplies, instruments, or equipment.

Status	Target Completion Date
In progress	September 2018

Recommendation 7. The Washington DC VA Medical Center Director confirms the full utilization of a Veterans Health Administration-authorized inventory system that contains accurate and reliable information regarding the availability of supplies throughout the Medical Center.

DC VAMC Acting Director Comments: Concur

Extensive processes are being implemented to ensure an accurate inventory as described in recommendation 1. As of December 31, 2017, the Medical-Surgical Primary inventory sites are scannable. Initially established periodic automatic replenishment (PAR) levels are being validated to ensure stock outages do not occur. All known items in the Medical-Surgical primary inventory point have now been entered into the Item Master Files and the Generic Inventory Package. All secondary inventory points will be set up for auto-generation within the Generic Inventory Package no later than June 30, 2018.

VHA and the VISN will oversee actions on this recommendation through the integrated oversight program described in recommendation 40. VHA will consider this recommendation complete when the Procurement and Logistics Office verifies that the site's inventory system contains accurate and reliable information regarding the availability of supplies throughout the Medical Center.

Status	Target Completion Date
In progress	December 2018

Recommendation 8. The Washington DC VA Medical Center Director makes certain that the environmental integrity of clean/sterile storerooms complies with Veterans Health Administration policy.

DC VAMC Acting Director Comments: Concur

To ensure the environmental integrity of the clean/sterile satellite storage areas and to ensure full compliance with VA policy, daily rounding by Environmental Management Services (EMS) and spot checks by Nursing staff of the areas were implemented. The medical center also placed monthly cleaning tracking sheets in all authorized clean supply rooms to track compliance. In addition, cleanliness reviews are conducted daily by Supply Distribution Techs to ensure the supply check lists are being utilized correctly. As of February 2018, the Deputy Logistics Chief and Expendable Inventory Supervisor conduct weekly rounds to visually inspect secondary inventory points and review cleanliness.

In spring of 2017 upon learning about this situation, the VISN Director immediately directed DC VAMC leadership to implement multiple actions to ensure clean/sterile storage areas are clean and in compliance with VHA policy. The VISN 5 Deputy Chief Medical Officer inspected each clean supply storage area, including those identified in the interim OIG report. Where cleanliness was identified as an issue, EMS was notified and took immediate action. The VISN 5 Deputy Chief Medical Officer followed-up to verify the rooms had been cleaned and confirmed all identified issues were addressed by DC VAMC.

The VHA Director of Environmental Programs Service conducted two site visits (May and November 2017). Thus, EMS created an action plan which is updated monthly. The visit in November by the Director of Environmental Programs was the final visit relating to the action plan. All issues were addressed to his satisfaction. There were 28 items initiated on the action plan, 20 of which are completed and closed. The remaining eight relate to six staffing vacancies (which are being addressed) and two items surrounding the relocation of EMS which is currently under construction.

DC VAMC will maintain a standing, accurate list of secondary inventory points that will include at a minimum: Location and Inventory Managers and Supply Technicians assigned to that location.

VHA policy requires compliance to environmental limits of reusable medical equipment storage areas by November 2022. DC VAMC is developing an action plan for this compliance and is deploying the TempTrak system that electronically monitors temperature and humidity inside units and rooms 24 hours per day, 7 days a week. Alerts will be provided to an escalation profile when the temperature and humidity controls exceed standards established for each given area. It is anticipated that this system will be fully deployed by June 1, 2018.

Status	Target Completion Date
In progress	June 2018

Recommendation 9. The Washington DC VA Medical Center Director ensures there are clearly defined and effective procedures for replacing missing or broken instruments, and that staff responsible for this function have been educated on the process.

DC VAMC Acting Director Comments: Concur

The acting DC VAMC Director, in collaboration with the National Program Office for Sterile Processing, directed Sterile Processing Service to develop a process to identify and remove from service any instruments which, after inspection, are discolored and/or do not appear to be in good repair and working order. The instrumentation is immediately pulled from service into a dedicated and clearly marked receptacle for further inspection and/or repair. The DC VAMC has a contracted vendor that inspects and refurbishes or repairs instruments. Instruments that need to be replaced are procured using a clearly defined process. All Sterile Processing staff has been trained in the proper procedure for disposition of instruments that are discolored or in need of repair. Ongoing education of this process will be provided to the Sterile Processing Service staff. Ongoing compliance with this process will be monitored through Facility and VISN-led inspections as well as monitoring non-conforming items through the monthly Reusable Medical Equipment Committee.

On November 4, 2017, the contractor spent one week on site inspecting instruments. The contractor examined 8,900 instruments, of which 216 were recommended for replacement. That is a 2.4 percent failure rate for damaged instrumentation. Ongoing contact with the contractor has not revealed a subsequent problem with stained or rusted instruments.

Completion of this recommendation will be determined through the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when the national program office and the VISN have independently validated that appropriate training is

complete and the facility processes for replacing broken or missing instruments demonstrates reliability over time.

Status	Target Completion Date
In progress	June 2018

Recommendation 10: The Washington DC VA Medical Center Director confirms that clearly defined and effective procedures address the disposition of discolored instruments during reprocessing and that staff responsible for this function have been educated on the process.

DC VAMC Director Comments: Concur

Disposition of discolored instruments will be managed through the same processes described in recommendation 9.

Status	Target Completion Date
In progress	June 2018

Recommendation 11. The Washington DC VA Medical Center Director ensures that the Sterile Processing Service implements a quality assurance program to verify the cleanliness, functionality, and completeness of instrument sets prior to their reaching clinical areas.

DC VAMC Acting Director Comments: Concur

The Acting Medical Center Director, in collaboration with the National Program Office for Sterile Processing, and the VISN 5 Patient Safety Officer, developed a Quality Assurance process which was implemented on November 2, 2017 to verify the cleanliness, functionality and completeness of instrument sets to assure that the sets are available when needed. The Quality Assurance process in place identifies non-conforming products not only in the Sterile Processing Service but also at the point of use. Any non-conformities are communicated to Sterile Processing in real time as well as data collected and aggregated. The Quality Assurance staff representative for Sterile Processing Service meets with the chief of Sterile Processing twice weekly to review Quality Assurance monitors. Overall compliance with the Quality Assurance process is monitored and tracked monthly in the Reusable Medical Equipment Committee meeting. Surgical specialties are reviewing surgical trays and updating of count sheets. The tray reviews and count sheet updates will be completed by April 1, 2018; it is anticipated that any identified missing instruments will be ordered.

Reusable Medical Equipment Committee will review data on non-conforming items monthly, with a goal of less than 2 percent noncompliance rate.

Follow-up on the implementation of this recommendation will be according to the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when we have evidence of an effective quality assurance for a full year.

Status	Target Completion Date
In progress	March 2019

Recommendation 12. The Washington DC VA Medical Center Director makes certain that Sterile Processing Service and operating room personnel comply with policies and procedures for the proper reprocessing of loaner instruments and trays.

DC VAMC Acting Director Comments: Concur

A new policy regarding the proper reprocessing of loaner instruments and trays was developed, published, and communicated to staff through training during Staff Meetings. In addition, the policy was reviewed by the facility Reusable Medical Equipment Committee, the committee that is charged with responsibility for monthly tracking of policy compliance. There is currently a process for reporting all non-conformities in the Reusable Medical Equipment Committee meeting; this data is reviewed monthly.

Status	Target Completion Date
In progress	September 2018

Recommendation 13. The Washington DC VA Medical Center Director verifies that Sterile Processing Service managers maintain an accurate Master List for reusable medical equipment and file copies of manufacturer's instructions as required by Veterans Health Administration policy.

DC VAMC Acting Director Comments: Concur

Sterile Processing Service will report on the accuracy of the facility master list monthly to the Reusable Medical Equipment Committee. Sterile Processing Service, in coordination with each clinical service, will verify that managers maintain an accurate Master List for reusable medical equipment and file copies of manufacturer's instructions as required by VHA policy.

In January 2018, DC VAMC leadership provided the most recent version of the inventory list of reusable medical equipment to the respective clinical services that use the equipment. Each service was instructed to coordinate with Sterile Processing Service to ensure that the inventory lists are accurate and up-to-date and that reusable medical equipment in the facility is counted. The services were also given target dates, such that a consolidated Master List by Service will be completed by April 30, 2018.

Compliance with accuracy of the Reusable Medical Equipment Master List will be validated through Facility and VISN led inspections as well as monitoring non-conforming items through the monthly Reusable Medical Equipment Committee.

Status	Target Completion Date
In progress	April 2018

Recommendation 14. The Washington DC VA Medical Center Director ensures that the Sterile Processing Service maintains updated and readily accessible standard operating procedures for all instruments and equipment within Sterile Processing Service and its satellite areas in accordance with Veterans Health Administration policy.

Acting DC VAMC Director Comments: Concur

Sterile Processing Service will report to the Reusable Medical Equipment Committee monthly regarding the maintenance of readily accessible standard operating procedures for all instruments and equipment within Sterile Processing Service and its satellite areas in accordance with VHA policy. Compliance with standard operating procedure completion will be validated through Facility and VISN led inspections as well as through the monthly Reusable Medical Equipment Committee.

DC VAMC, together with staff from the Sterile Processing Service National Program Office, conducted an initial review to update/complete Standard Operating Procedures and Documentation books for all instruments and equipment within Sterile Processing Service and its satellite areas in accordance with VHA policy. Once completed, the standard operating procedures were organized and stored in a readily accessible section of the Sterile Processing Service. A current Lean Process Improvement plan was begun to ensure that the Sterile Processing Service remains updated. A comprehensive review of reusable medical equipment in all areas of the facility and associated standard operating procedures is currently underway. A need for standard operating procedure revision or development will be completed during this comprehensive review. The target date for completion for all standard operating procedures is May 31, 2018. In order to demonstrate that the SOPs remain updated and readily accessible after completion, ongoing monitoring will occur at the DC VAMC and VISN-led Sterile Processing Service inspections through the end of September 2018.

Status	Target Completion Date
In progress	September 2018

Recommendation 15. The Washington DC VA Medical Center Director verifies that all Sterile Processing Service employees have appropriate, updated competencies and a demonstrated proficiency to perform their assigned duties.

DC VAMC Acting Director Comments: Concur

Sterile Processing Service will report the Reusable Medical Equipment Committee monthly regarding the status of competencies and proficiencies of the Sterile Processing Service employees. Ongoing compliance with competencies will be validated by competency audits incorporated into Facility and VISN led Service Processing Service inspections.

Staff from the National Program Office for Sterile Processing (NPOSP) provided on-site training to all Sterile Processing Service staff, including contract technicians, during the week of December 4, 2017. Since that training, there are staff trained with appropriate competencies to work in all areas where there is Sterile Reprocessing occurring. Competency validation, however, is an ongoing process. New staff, as a part of their Service Level Orientation process will have appropriate training and competency validation prior to independently performing reprocessing. As new equipment or instrumentation is acquired and as standard operating procedures are updated or new standard operating procedures are implemented, staff that use the equipment or instrumentation will have training with competency validation. Annually a competency based risk analysis is completed to identify which competencies will be validated annually, biannually and every three years. Sterile Processing Service staff perform competency

validation by direct observation of a particular skill. The medical center staff, together with NPOSP developed an action plan to continually update standard operating procedures and subsequently train and validate competency for any staff members in need of area-specific training, or who are newly hired. A comprehensive review of reusable medical equipment and associated standard operating procedures and competency validation is currently underway. Any gaps in competency validation related to the standard operating procedures will be corrected with staff training and competency validation. The target date for completion for all standard operating procedures and Competency validation is May 31, 2018.

Status	Target Completion Date
In progress	May 2018

Recommendation 18. The Washington DC VA Medical Center Director ensures the revision of Medical Center Fiscal Service practices to eliminate unnecessary cessations of prosthetic device purchasing, including at fiscal year-end.

DC VAMC Acting Director Comments: Concur

At the end of FY 2017 there was no disruption of prosthetic ordering due to lack of funds.

The Acting Medical Center Director will ensure the acting Chief, Prosthetic & Sensory Aids Service (PSAS) work with Fiscal Service to establish a process for managing the availability of transaction numbers in the financial management systems (VISTA/IFCAP) of Prosthetic fund control points to support the operational needs of the facility and the specific care needs of Veterans. The target completion date of this standard operating procedure is March 31, 2018.

The DC VAMC Acting Chief, PSAS collaborated with the acting Chief, Fiscal Service to understand the contributing factors impacting prosthetic device purchasing and establish corrective actions. The contributing factors were failure to track the status of available transaction numbers for Prosthetic fund control points and failure to establish proper end-of-year close out procedures. The acting Chief, PSAS established a quarterly budget with adequate funding based on previous year data and is actively working with Fiscal Service to continue tracking data transactions to prevent disruption of purchasing due to availability of purchase order numbers.

Status	Target Completion Date
In progress	March 2018

Recommendation 21. The Washington DC VA Medical Center Director transitions purchase cards held by clinical staff and used for expendable medical supplies to Logistics Service staff, while ensuring that medical supplies can be obtained in a timely manner.

DC VAMC Acting Director Comments: Concur

The DC VAMC has already begun removing purchase cards held by clinical staff, transitioning those cards to Logistics service in a way that clinical services are not disrupted. DC VAMC Logistics leadership will conduct a workload-based analysis to ensure an appropriate number of

purchasing agents in Logistics service. DC VAMC will ensure new purchase card holders have completed a comprehensive training and new staff receive training prior to receiving purchase cards in accordance with VHA policy. DC VAMC is in the process of reviewing Medical/Surgical Prime Vendor utilization as well as purchase card transaction history as a way of verifying that medical supply items are added to the Medical/Supply Prime Vendor formulary and that the Medical/Supply Prime Vendor is being utilized to procure supplies whenever appropriate to do so in lieu of open market purchases via purchase cards.

As of February 7, 2018, DC VAMC has pulled back any unnecessary purchase cards and [n]ow there are fewer than 125 purchase cards (down from 283 as identified by OIG).

Status	Target Completion Date
In progress	June 2018

Recommendation 22. The Washington DC VA Medical Center Director ensures that medical supply items are added to the prime vendor formulary in order to meet prime vendor purchasing goals.

DC VAMC Acting Director Comments: Concur

The DC VAMC Resource Council will oversee compliance with Medical/Surgical Prime Vendor utilization on a quarterly basis.

As of December 31, 2017, once the Generic Inventory Package was established in the Primary Supply point, medical supply items were added to the prime vendor formulary. DC VAMC is still in the process of finalizing the secondary supply areas, which are anticipated to be completed June 30, 2018. As newly identified items are recognized, they will also be added to the prime vendor formulary. DC VAMC is in the process of reviewing Medical/Surgical Prime Vendor utilization as well as purchase card transaction history as a way of verifying that medical supply items are added to the formulary and that the Medical Supply Prime Vendor is being utilized to procure supplies whenever appropriate to do so.

Status	Target Completion Date
In progress	June 2018

Recommendation 23. The Washington DC VA Medical Center Director makes certain that the Purchase Card Coordinator and approving officials monitor the issuance and future use of government purchase cards in accordance with VA Financial Policy.

DC VAMC Acting Director Comments: Concur

The DC VAMC Resource Council will oversee purchase card utilization and compliance on a quarterly basis. DC VAMC staff will review the list of purchase card holders once per quarter to ensure that the list is accurate and updated as to staff that may leave the facility as well as newly hired staff. Existing staff will receive comprehensive training regarding the VA Financial Policy regulations for purchase cards. Newly hired staff who will be expected to have a purchase card will receive the training following orientation and prior to issuance of purchase cards. To track

resourcing in the future use of purchase cards, DC VAMC will conduct a workload-based analysis at least twice annually to ensure an appropriate number of purchasing agents are present in Logistics service. Purchasing workload is in the process of being transitioned to the Logistics service and the final removal of purchase cards from clinical services staff will be completed by March 31, 2019.

Status	Target Completion Date
In progress	March 2019

Recommendation 24. The Washington DC VA Medical Center Director maintains segregation of duties between personnel who order and purchase expendable and nonexpendable items and those who receive the items.

DC VAMC Acting Director Comments: Concur

The DC VAMC has segregated duties between the personnel who order and purchase expendable and nonexpendable items (purchasing agents and ordering officers) and those that receive these items (warehouse receiving staff). This was accomplished through clarifying assignment of duties, ensuring receiving staff were not involved in the purchase/order of items.

Status	Target Completion Date
Complete	August 2017

Recommendation 26. The Washington DC VA Medical Center Director ensures that equipment is accurately and timely entered into the Automated Engineering Management System/Medical Equipment Reporting System.

DC VAMC Acting Director Comments: Concur

The DC VAMC Equipment Committee will review utilization compliance with Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) on a semi-annual basis.

Strategic Solutions Inc. conducted an inventory of non-expendable assets in April 2017. Over 1,000 items were not found in the AEMS/MERS. In order not to disrupt daily operations, assets will be entered into AEMS/MERS during off-hours. All assets are expected to be entered into AEMS/MERS no later than September 30, 2018. Patient care areas such as the Operating Room will be prioritized.

A process review was conducted and assets are now being entered upon receipt. A notification was provided to remind clinical stakeholders that Logistics must be alerted if a piece of equipment is received in the service without an asset tag.

Starting in April 2017, emergent, over-the-shoulder training was conducted with staff in the use of AEMS/MERS system. One staff member attended formal classroom-based training January 30-February 1, 2018. As of February 8, 2018, five non-expendable staff also need to attend formal, classroom-based AEMS/MERS training. Two staff are scheduled for March 2018 and the remaining staff attendance will be staggered to ensure coverage to be completed no later than

September 30, 2018. In the future, all new non-expendable staff will have formal AEMS/MERS training as part of their first-year training curriculum requirements.

Status	Target Completion Date
In progress	September 2018

Recommendation 27. The Washington DC VA Medical Center Director ensures that unrequired equipment is turned-in for disposition consistent with Veterans Health Administration policies and procedures.

DC VAMC Acting Director Comments: Concur

Following the interim OIG report, the acting Medical Center Director, in collaboration with the acting Under Secretary for Health and the VISN 5 Network Director took immediate action to arrange the orderly movement of goods and supplies from the warehouse to minimize losses to the Government. Logistics Service has been directed that no new assets are permitted to be transitioned to the external warehouse as of February 1, 2018.

A Logistics Management Specialist was assigned to conduct a review of the equipment and other VA property housed at the off-site warehouse. On November 1, 2017, the off-site warehouse inventory and reconciliation were completed. All items within the warehouse have been reallocated, disposed of as unsalvageable waste, or placed on the General Services Administration Excess List. All excess equipment is anticipated to be cleared out of the warehouse no later than April 2, 2018. This is based on the timeframe that items are published within the GSA website.

Moving forward, DC VAMC will provide comprehensive training on turn-ins to all staff involved in the turn-in process by March 30, 2018 to ensure equipment turn-in will comply with VHA policies and procedures.

The acting Medical Center Director, in collaboration with the former acting Under Secretary for Health and the VISN 5 Network Director, also took immediate action to create an inventory and establish accountability over the equipment and supplies in the both the on-site and off-site warehouses.

Follow-up on the implementation of this recommendation will be according to the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when we have evidence all staff are trained in turn-in process and evidence of compliance with the equipment turn-in process for a full year.

Status	Target Completion Date
In progress	March 2019

Recommendation 28. The Washington DC VA Medical Center Director properly secures all areas used to store medical equipment and supplies.

DC VAMC Acting Director Comments: Concur

Security assessments were conducted by the newly hired Chief of Police who made recommendations regarding controlled access to storage sites at the main facility. Security

improvements instituted included: ensuring secured areas were locked; restricting access to the warehouse, including removal of badge access for employees that did not require it; review of all warehouse cameras and repairing/replacing cameras that were not working. Moving forward, DC VAMC will review all supply and equipment storage areas and ensure areas have been secured in accordance with VHA guidelines.

Follow-up on the implementation of this recommendation will be according to the integrated oversight process described in recommendation 40. VHA will consider this recommendation complete when the facility provides evidence that storage sites have been inspected and properly secured for a period of 6 months.

Status	Target Completion Date
In progress	September 2018

Recommendation 29. The Washington DC VA Medical Center Director designates an official records manager, alternate records manager, and official records liaisons as well as implements a records management program in accordance with the National Archives and Records Administration requirements.

DC VAMC Acting Director Comments: Concur

The DC VAMC Acting Director has designated individuals for the Acting Records Manager position and for the Alternate Records Manager position. The Records Manager position is in recruitment for permanent hire.

The acting Records Manager is ensuring that each service has an official Records Liaison Officer. To date, 84 percent of Services have a Records Liaison Officer. By February 28, 2018, DC VAMC will ensure that 100 percent of services have identified a Records Liaison Officer that has received appropriate training.

DC VAMC is in the process of implementing a records management program in accordance with the National Archives and Records Administration requirements. DC VAMC has created a SharePoint for Records Management to ensure transparency amongst the organization, which includes a directory of the Records Liaison Officers and all necessary policies and regulations for reference. DC VAMC will have a fully operational records management program no later than June 1, 2018 in accordance with VHA policy.

Status	Target Completion Date
In progress	June 2018

Recommendation 30. The Washington DC VA Medical Center Director verifies that actions have been taken to notify patients when their information may have been improperly accessed, as appropriate.

DC VAMC Acting Director Comments: Concur

The Privacy Officer determined that there was not a need to notify Veterans because there was no evidence of improper access to their patient information. In the future, if the Privacy Officer

discovers any evidence of improperly accesse[d] patient information, the Privacy Officer will make the necessary notifications to Veterans.

The Acting DC VAMC Director hired a permanent Privacy Officer on September 3, 2017. The facility policy, PM 002-09 Privacy Policy, aligns with VA Handbook 6500.2 and is available for all employees. The policy is reviewed annually for revision. Within one hour of discovery, data breaches are to be reported to the facility Privacy Officer via vhawasfoia@va.gov during normal business hours. Incidents that occur after hours are to be reported to the VA-NSOC. All incidents are to be entered in to the Privacy and Security Event Tracking System (PSETS) in accordance with VA Handbook 6502.01, Privacy Event Tracking. The Privacy Officer continues to provide education and increase awareness to ensure that VA staffs and patients are aware of who to contact should there be an issue or concern. It is anticipated that staff education will be complete by April 28, 2018. This is tracked and monitored through Quality, Safety, and Value Executive Council.

Status	Target Completion Date
In progress	April 2018

Recommendation 31. The Washington DC VA Medical Center Director verifies that accurate and complete financial documentation to support medical supply and equipment purchases is readily available in accordance with GAO *Standards for Internal Control in the Federal Government*.

DC VAMC Acting Director Comments: Concur

The DC VAMC Resource Council will oversee compliance with financial controls and documentation on an annual basis. DC VAMC Chief Logistics Officer and Chief Fiscal Officer, along with VISN subject matter experts in fiscal and logistics will conduct oversight to ensure financial training and controls are in place. DC VAMC staff has been trained in proper procedures for management of purchase orders, including reconciliations. DC VAMC will review training with staff involved in supply and equipment purchases in financial documentation requirements by April 1, 2018.

Status	Target Completion Date
In progress	April 2018

Appendix F: OIG Contact and Staff Acknowledgments

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