



Testimony

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Representatives

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VA SURGICAL IMPLANTS

Shortcomings in Implant Purchasing and Tracking

Statement of Randall B. Williamson
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Chairman Coffman, Ranking Member Kirkpatrick, and Members of the Subcommittee:

We are pleased to be here today to discuss our work on the purchase and tracking of surgical implants at Department of Veterans Affairs (VA) facilities. VA's Veterans Health Administration (VHA) is one of the largest purchasers of surgical implants, which include biological implants, such as skin and bone grafts, and non-biological implants, such as cardiac pacemakers and artificial joints. VHA spent about \$563 million on surgical implants in fiscal year 2012, an increase of 28 percent since fiscal year 2008. Surgeons and other clinicians at VA medical centers (VAMC) determine veterans' needs for surgical implants, request the implant of their choice for purchase, and perform the clinical procedures to implant the items. While VA has negotiated competitive contracts for a variety of implants, VAMCs or VHA's regional network contracting offices (NCO) can purchase a specific surgical implant requested by a clinician from the open market with appropriate clinical justification, rather than purchasing a similar item through a VA-negotiated competitive contract.¹ Upon purchase, identifying information is recorded, such as the serial and lot numbers of the item, which can be used later to identify veterans who received a particular implant if one is recalled by a manufacturer or the Food and Drug Administration due to safety concerns.

At a May 2012 hearing of this subcommittee, concerns were raised about the extent to which VAMCs and NCOs purchase surgical implants from the open market without appropriate justification, as well as VHA's oversight of surgical implant purchases.² More recently, members of Congress raised concerns about VHA's ability to identify patients who received a surgical implant that was subjected to a recall and raised allegations about vendor representatives providing direct patient care to veterans at three VAMCs. My remarks today will address the following two areas: (1) VAMC compliance with VHA requirements for documenting

¹VA negotiates national, regional, and local competitive contracts with vendors for all types of items—including surgical implants. Items that are not purchased from these contracts are referred to as open-market purchases. There are 21 NCOs throughout VHA's health care system that manage the contracting activities of the VAMCs within each of VHA's 21 Veterans Integrated Service Networks. These networks oversee the day-to-day functions of VAMCs that are within their network.

²*Purchasing Perspective: VA's Prosthetics Paradox, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Veterans' Affairs, 112th Cong. (2012).*

surgical implants purchased from the open market, and VA and VHA oversight of compliance with these requirements; and (2) VHA's ability to identify veterans who received an implant that is being recalled by the manufacturer or the Food and Drug Administration. My remarks on surgical implant purchasing and VHA's ability to identify veterans who received recalled implants are based on our report, released earlier this week, entitled *VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement*.³ For this report, we visited four VAMCs that serve large veteran populations and assessed compliance with VHA requirements by reviewing a diverse selection of 257 surgical implant purchases from different vendors. The purchases we reviewed represented from about 6 percent to about 83 percent of the applicable purchases at each VAMC in the first 6 months of fiscal year 2013.⁴ While these results cannot be generalized to all VAMCs, they provide insight into VAMC and NCO compliance. We also interviewed officials from VA, VHA, and from four networks, which oversee VAMCs, and reviewed pertinent statutes, regulations, and VA and VHA documents. Furthermore, we reviewed agency documents and interviewed VA and VHA officials on VHA's processes for tracking surgical implants placed in patients. Our work was performed in accordance with generally accepted government auditing standards. Further details on our scope and methodology are included in our report.

GAO also investigated an allegation that surgical implant vendor representatives had participated in direct patient care at three VAMCs. The results of our investigation are summarized in appendix I. Our investigative work was conducted from February 2013 to January 2014 in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency, as further detailed in appendix I. During our investigation, we conducted field interviews, performed document reviews, and reviewed relevant policies and procedures relative to the allegations presented.

³GAO, *VA Surgical Implants: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement*, [GAO-14-146](#) (Washington, D.C.: Jan. 13, 2014).

⁴The range in percentages is the result of large differences in the number of open-market purchases at each VAMC.

We provided VA with a draft of this statement. VA provided one technical comment, which we incorporated.

Surgical Implant Purchase Requirements Were Not Always Followed at Selected VAMCs, and VA and VHA Oversight Needs Improvement

Our work at four VAMCs found that these VAMCs did not always follow VHA requirements for documenting open-market purchases of surgical implants. Specifically:

- None of the four VAMCs fully complied with VHA requirements for obtaining waivers required for open-market purchases of surgical implants because they were focusing on other priorities or lacked awareness of the requirements, among other factors.⁵
- None of the four VAMCs fully complied with additional VHA requirements for documenting open-market purchases that are part of a new process VHA implemented in fiscal year 2013 for surgical implant purchases above the Federal Acquisitions Regulation's micro-purchase threshold of \$3,000 and below its simplified acquisition threshold of \$150,000.⁶ VAMC and regional office officials attributed noncompliance mainly to insufficient VHA guidance and VA staff's inexperience in completing these requirements.⁷
- Three of the four VAMCs did not comply with a VHA requirement pertaining to agreements with vendors that provided surgical implants

⁵VHA policy stipulates that all open-market purchases of non-biological implants require a waiver approved by the VAMC Chief of Staff when a comparable item would have been available through a VA-negotiated national committed-use contract. At two of the VAMCs we visited, VHA data indicated that waivers were not being completed for open-market purchases of non-biological implants when a comparable item would have been available through a national committed-use contract. At the other two VAMCs, we selected 20 and 30 purchases for which VHA data indicated that such waivers were on file and reviewed whether those waivers were on file and whether they were complete. All open-market purchases of biological implants require a waiver by VHA's Procurement and Logistics Office when a decision is made to purchase an item from the open market rather than from a Federal Supply Schedule contract. At each VAMC, we selected 20 to 30 purchases of biological implants that, based on VHA data, appeared to have been purchased from the open market for review. For the open-market purchases, we assessed whether a waiver was obtained for those purchases, and if so, whether the waiver was complete.

⁶We reviewed between 15 and 28 purchases over \$3,000 at each VAMC we visited.

⁷If a clinician requests a surgical implant over \$3,000 from the open market, the following are required: (1) a statement affirming that the vendor's price was fair and reasonable and the basis for this determination; and (2) a justification for other than full and open competition that cites the legal authority for purchasing a surgical implant where the VAMC solicited only one source in making the open-market purchase.

to them on consignment. Under a consignment agreement, the vendor maintains vendor-owned items at the VAMC, and the VAMC purchases only the items actually used. A consignment agreement may be useful when the requirement for a surgical implant is immediate and it is not possible to predetermine which of several types or models are required. These agreements, which clinicians likely established to ensure timely access to implants, did not comply with a VHA requirement that consignment agreements must be authorized by a VHA contracting officer.

The lack of full compliance with these requirements limits VHA's ability to determine why VAMCs are purchasing surgical implants from the open market and VHA's ability to ensure that it is paying a fair and reasonable price for surgical implants. To improve compliance with VHA requirements, in our report, we recommended that the Secretary of Veterans Affairs take several actions, including providing clear guidance to VAMCs on when and how to complete required waivers, establishing internal controls to ensure VAMCs' compliance with waiver requirements, and providing additional training on how to properly document open-market purchases over \$3000.⁸ VA concurred with our recommendations and noted that VHA's Procurement and Logistics Office will emphasize the waiver process through webinar trainings and standard operating procedures guidance, and it will develop a checklist for documentation of open-market surgical implant purchases over \$3,000.

In addition, we found that VA and VHA's oversight of surgical implant purchases to detect and correct instances of noncompliance needs improvement. Specifically:

- Although VA and VHA have recently begun conducting oversight of surgical implant purchases over \$3,000 to assess compliance with VHA's new requirements, VHA officials told us that they have not ensured that corrective action has been taken to address identified noncompliance because of poor communication between VA and VHA and insufficient staffing to follow up on identified issues. VA's Office of Acquisition and Logistics did not provide VHA with information on the VAMCs at which noncompliance was identified, according to a senior VHA official. The official also explained that VHA's policy is largely intended to be consultative in nature and that

⁸[GAO-14-146](#).

VHA's Procurement and Logistics Office is not sufficiently staffed to ensure that corrective action is taken.

- Moreover, VHA assesses each VAMC's performance on metrics established for surgical implant purchasing, such as the extent to which VAMCs purchased surgical implants from a national committed-use contract or obtained a waiver allowing clinicians to use an alternative item. However, as of November 2013, VHA did not have a policy governing how any identified deficiencies should be addressed and the corrective actions necessary for VAMCs and VHA's regional networks to take. Absent such a policy, the degree of monitoring and corrective actions taken varied among the four networks we visited. Network prosthetics officials at two of the four networks told us that they regularly monitored the results from VHA's assessments and took steps to ensure that VAMCs address identified deficiencies, such as correcting data-entry errors. In the other two networks that did not ensure that VAMCs address deficiencies, VHA's metrics identified a relatively high rate of noncompliance with surgical implant purchases from VA-negotiated national committed-use contracts. In one of these networks, this noncompliance included a high percentage of purchases missing serial numbers or lot numbers, which has potentially significant patient safety and cost implications.

Without ensuring that noncompliance with purchasing requirements or deficiencies in performance measures are appropriately addressed, VA and VHA run the risk of these issues recurring or continuing. To address this shortcoming, our report recommended that VHA revise existing guidelines to require that VAMCs and NCOs document the measures they are taking to address noncompliance and report their progress (via corrective action plans) in achieving those measures through the VHA and VA management chains of command.⁹ VA concurred with our recommendation and stated that VHA will require documentation of measures taken to address noncompliance identified in audits.

⁹[GAO-14-146](#).

VHA Is Limited in Its Ability to Identify and Locate Patients Who Receive a Surgical Implant

We also noted that VHA is limited in its ability to identify and locate patients who receive an implant, which is particularly important in the event of a recall by the manufacturer or the Food and Drug Administration because of safety concerns. For example, VA has noted instances across its health care system where lot numbers and serial numbers for such purchases were not entered into the prosthetics purchasing system and has initiated corrective actions, although these actions appear stalled as of December 2013.¹⁰

Specifically, in 2008, VA's Office of Information Technology began developing the Veterans Implant Tracking and Alert System (VITAS), which was designed to track and retrieve identifying information—including the lot and serial number—of surgical implants placed in patients VHA-wide. VITAS was developed to address identified shortcomings in VHA's existing ability to track surgical implants. According to VHA, these shortcomings include the following:

- The lot number and serial number of items implanted in patients is not always entered into the prosthetics purchasing system by purchasing and procurement staff, as required.
- While VHA clinicians from most specialties track identifying information of items implanted in their patients using standalone systems or spreadsheets that are particular to the clinicians' specialties, VA found that information on surgical implants recorded in these systems is neither standardized nor is it shared across VAMCs. Furthermore, VA found that identifying information on surgical implants used in certain clinical specialties, including gastroenterology, interventional radiology, and pulmonary, is not tracked in any system.¹¹

According to VA and VHA officials involved in the development of VITAS, this system's development was suspended as of the end of fiscal year 2012 due to data-reliability challenges stemming from inaccurate or missing entries in the prosthetics purchasing system and interoperability

¹⁰The prosthetics purchasing system is used to record the purchase of all prosthetics, including surgical implants.

¹¹According to VA, for these clinical specialties VHA was unable to verify that the items purchased by the prosthetics department were actually implanted in the patients for which they were purchased.

challenges between VITAS and other VHA systems that store information on surgical implants. VA and VHA are in the process of reevaluating VITAS; however, as of December 2013, VA and VHA had not decided whether to resume the development of VITAS. As a result, VHA's ability to identify and locate patients who received an implant remains limited.

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

For questions about this statement, please contact Randall B. Williamson at (202) 512-7114 (williamsonr@gao.gov). Individuals making key contributions to this testimony and the report on which it is based include Wayne McElrath, Director; Gary Bianchi, Assistant Director; Kim Yamane, Assistant Director; Ashley Dixon; Cathleen Hamann; Julie Spetz; and Michael Zose.

Appendix I: Patient Care Provided by Vendor Representatives at Department of Veterans Affairs Medical Centers (VAMC)

This appendix summarizes the results of the investigative work we conducted to review an allegation that surgical implant vendor representatives had participated in direct patient care at three VAMCs by applying skin grafts to patients or debriding patients' wounds. We visited the three VAMCs at which the alleged actions had occurred and interviewed clinical staff, such as physicians, and nonclinical staff, including hospital administrators, to determine whether vendor representatives had participated in direct patient care, and, if so, the circumstances under which the direct patient care occurred. At each of the three VAMCs, we also reviewed documentation, such as VAMC vendor policies and clinical progress notes, which document patient care episodes. Furthermore, we interviewed vendor representatives who provided skin graft products to these VAMCs. The findings from these three VAMCs are not generalizable to other types of surgical implants, to other clinicians, or to other VAMCs. We did not identify the frequency of vendor representatives participating in the provision of direct patient care for all types of surgical implants at the VAMCs we visited, or for the Veterans Health Administration (VHA) as a whole. We conducted this investigative work from February 2013 to January 2014 in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency.

Results of Investigation

We were able to affirm that, in some instances, vendors were participating in direct patient care at one of the three VAMCs we investigated, as recently as August 2013. At the two other VAMCs, we were unable to affirm these allegations. Specifically, several clinicians at one VAMC stated that vendor representatives applied skin grafts to patients or assisted Department of Veterans Affairs (VA) clinicians with the application of skin grafts on multiple occasions. Patients' clinical progress notes we obtained from this VAMC confirmed that a vendor representative had applied skin grafts to several patients or assisted in the application of the grafts. One physician assistant who disclosed that a vendor representative had occasionally assisted in the application of skin grafts stated that vendor representatives may have assisted with this procedure because the VAMC lacked available clinical staff to provide such assistance. A physician who stated that vendor representatives were present during the application of skin grafts at this VAMC told us that he did not know what the official vendor policy was at the VAMC, and he was not aware of a VAMC policy that addressed vendor roles.

Our review indicates that VA allows vendor representatives who supply an implant to be present during a surgical procedure—in which an implant is placed in a veteran—and to provide technical assistance to the clinical staff. We also found that VHA’s policy governing vendor access to VAMCs and involvement during clinical procedures is broad in nature. It requires each VAMC to develop its own procedures on vendor access and does not provide guidance on what these procedures should entail. Based on the written procedures we reviewed and interviews with officials at the three VAMCs we visited, we found varying degrees of specificity in current local procedures governing vendor access and participation in patient care. For example:

- At two VAMCs, officials stated that the local procedures require background screening (for possible criminal history) for vendor representatives who are present in clinical areas; the third VAMC had no such requirement.
- At one VAMC, written procedures also prohibited vendors from providing direct patient care, specifying that “vendors will not ‘scrub in’ or physically perform any part of a procedure”; the other two VAMCs had no such prohibition.

Moreover, we found that the VAMC where we affirmed that vendors were participating in direct patient care was not in compliance with its written procedures covering vendor access to the facility. According to an official from the VAMC director’s office, no documentation was on file regarding vendor qualifications, training, and other certifications and competencies for the vendor representatives who are present in clinical areas at this VAMC. This is not in compliance with the VAMC’s procedures that require that such information must be maintained on file for all vendor representatives who are present in clinical areas at the VAMC.

Our findings on vendor involvement in patient care at the three VAMCs we visited cannot be generalized to VHA as a whole. However, our findings raise questions about the extent of vendor involvement in patient care at other VA facilities. Accordingly, we plan to refer the specific cases we found on vendor involvement in direct patient care to the VA Office of the Inspector General for further investigation if deemed appropriate.

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