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VA SURGICAL IMPLANTS

Purchase
Requirements Were
Not Always Followed
at Selected Medical
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Why GAO Did This Study

VHA spending on surgical implants—such as stents and bone and skin grafts—has increased to about \$563 million in fiscal year 2012. Clinicians at VAMCs determine veterans' needs and request implant purchases either from a contract or from the open market (i.e., not from an existing contract). VHA requirements—which implement relevant federal regulations—include providing justifications for open-market purchases.

GAO was asked to evaluate implant purchasing by VHA. This report examines (1) factors that influence clinicians' decisions to use particular implants when multiple, similar items are available; (2) selected VAMCs' compliance with pertinent VHA requirements for documenting open-market purchases; and (3) VA's and VHA's oversight of VAMC compliance with implant purchasing requirements. GAO visited four VAMCs that serve large veteran populations and are dispersed geographically. GAO interviewed clinicians at the VAMCs, reviewed pertinent statutes, regulations, and policies and reviewed a sample of implant purchases from different vendors. These results cannot be generalized to all VAMCs but provide insights. GAO also interviewed VA and VHA officials and reviewed agency documents.

What GAO Recommends

GAO recommends that VA identify implants and establish a timeline to expand the volume that can be purchased from VA-negotiated contracts and improve compliance with and oversight of purchasing requirements. VA concurred with these recommendations.

View [GAO-14-146](#). For more information, contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov.

What GAO Found

Clinicians at the four Department of Veterans Affairs Medical Centers (VAMC) GAO visited said that patient need and their clinical expertise were the main factors influencing their decisions of which surgical implants to use. Also, clinicians in certain specialties said they typically used one of the implants available on VA-negotiated national committed-use contracts, which generally establish a fixed price for several models of nine types of surgical implants that the Veterans Health Administration (VHA) commits to using nationally. VHA recognizes the need for expanding items covered under these contracts to fully leverage its purchasing power but, as of October 2013, had not identified additional implants to include on such contracts or established timelines for doing so. GAO also found that the availability of implants on VA-negotiated federal supply schedule (FSS) contracts rarely influenced clinicians' decisions on which implant to use. Clinicians were often not aware of the availability of surgical implants on FSS contracts, which are negotiated by one of VA's contracting offices, but for which VHA clinicians have little or no input. Clinicians told GAO that in some cases they may avoid implants on FSS contracts due to their concerns about the quality of these items.

In regard to compliance with VHA's requirements for justifying open-market purchases of surgical implants, which VHA adopted to promote adherence to relevant federal regulations, GAO found the following:

- None of the four VAMCs fully complied with requirements for obtaining waivers for open-market purchases of surgical implants because they were focusing on other priorities or lacked awareness of the requirements, among other factors.
- None of the four VAMCs fully complied with additional requirements for documenting open-market purchases that are part of a new process VHA implemented in fiscal year 2013 for surgical implant purchases over \$3,000. VAMC and regional office officials attributed noncompliance mainly to insufficient VHA guidance and VA staff's inexperience in completing these requirements.
- Three of the four VAMCs did not comply with a VHA requirement pertaining to agreements with vendors that provided surgical implants to them on consignment. These agreements, which clinicians likely established to ensure timely access to implants, do not comply with a VHA requirement that consignment agreements must be authorized by a VHA contracting officer.

The Department of Veterans Affairs (VA) and VHA have begun conducting oversight of surgical implant purchases over \$3,000 to assess compliance with VHA's new requirements. However, VHA officials told GAO that VA and VHA 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. Furthermore, VHA assesses each VAMC's performance on metrics established for surgical implant purchasing, but it does not have a policy governing how any identified deficiencies should be addressed nor the corrective actions to be taken by VAMCs and VHA's regional networks.

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Abbreviations

| | |
|-------|--|
| eCMS | Electronic Contract Management System |
| FAR | Federal Acquisition Regulation |
| FSS | Federal Supply Schedule |
| JOFOC | Justification for other than full and open competition |
| NCO | Network contracting office |
| NPPD | National Prosthetics Patient Database |
| VA | Department of Veterans Affairs |
| VAAR | VA Acquisition Regulation |
| VAMC | VA medical center |
| VHA | Veterans Health Administration |
| VITAS | Veterans Implant Tracking and Alert System |

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January 13, 2014

The Honorable Mike Coffman
Chairman
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
House of Representatives

The Honorable Bill Johnson
House of Representatives

The Department of Veterans Affairs (VA) 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. Surgical implants fall under VHA's definition of prosthetics, which includes all items that support or replace a body part or function.¹ Federal law grants the Secretary of VA the authority to procure prosthetics and related necessary services in such manner as the Secretary may determine to be proper, without regard to any other provision of law.² VHA has exercised this authority to limit competition when purchasing prosthetics—including surgical implants—when doing so is necessary to meet veterans' clinical needs. Specifically, surgeons and other clinicians at VA medical centers (VAMC) determine veterans' needs for surgical implants. While VA has negotiated competitive contracts for a variety of surgical 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 competitive contract.³ VHA's spending on surgical implants

¹VHA's definition of prosthetics includes items worn by the veteran, such as an artificial limb or hearing aid, as well as surgical implants.

²38 U.S.C. § 8123.

³VHA 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.

increased about 28 percent over the last four years and was about \$563 million in fiscal year 2012.

At a recent congressional hearing, concerns were raised about the extent to which VAMCs and NCOs purchase surgical implants from the open market without appropriate justification, rather than purchasing such items from competitive contracts—potentially at a lower cost.⁴ Concerns were also raised about VHA's oversight of VAMCs' and NCOs' purchases of surgical implants, which may have allowed insufficiently documented purchases of these items to go unnoticed. You asked us to review VHA's purchasing of surgical implants, including requirements for documenting purchases from the open market and oversight of compliance with these requirements. This report examines

1. Factors that influence clinician decisions to use particular surgical implants when multiple, similar items are available;
2. Compliance at selected VAMCs with pertinent VHA requirements for documenting surgical implant purchases from the open market; and
3. VA and VHA oversight of compliance with surgical implant purchasing requirements.

To examine the factors that influence clinician decisions to use particular surgical implants when multiple, similar items are available, we visited VAMCs in four locations: Indianapolis, Indiana; Los Angeles, California; New York, New York; and Seattle, Washington.⁵ At each of the four VAMCs, we interviewed at least one clinician from each of six clinical specialties that typically use surgical implants to obtain information on the factors they consider when choosing which surgical implant to use when multiple, similar types of implants are available.⁶ In total, we interviewed

⁴*Purchasing Perspective: VA's Prosthetics Paradox, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Veterans' Affairs, 112th Cong. (2012).*

⁵We selected these four VAMCs because they are all classified by VHA as surgically complex facilities, all serve large veteran populations, and are each located in a different network. VAMCs that are assigned a complex rating require special facilities, equipment, and staff for difficult operations, such as cardiac surgery. Each of the VAMCs we visited served more than 50,000 unique patients in fiscal year 2012.

⁶The six clinical specialties we selected included cardiology or cardiac surgery; general surgery; orthopedic surgery; neurosurgery; podiatry; and vascular surgery.

28 clinicians. In addition, we interviewed staff, such as the operating room nurse manager, involved in managing surgical implants at the VAMCs.

To assess compliance at the four selected VAMCs with pertinent VHA requirements for documenting surgical implant purchases from the open market, we first identified the applicable requirements. To do so, we reviewed VA's statutory authority to acquire prosthetics—including surgical implants, applicable federal regulations—including the Federal Acquisition Regulation (FAR) and VA Acquisition Regulation (VAAR) and implementing guidance issued by VA and VHA with respect to surgical implant purchasing.⁷ To learn more about VA's and VHA's surgical implant purchasing processes for surgical implant purchases from the open market, we also interviewed procurement and prosthetics officials at VA and VHA. To determine compliance with pertinent requirements, applicable to surgical implant purchases from the open market at each of the four VAMCs we visited, we reviewed documentation related to selected purchases that occurred in the first 6 months of fiscal year 2013. We reviewed the VHA data from which we selected 257 purchases. We selected these purchases to obtain a diverse group of 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 2013.⁸ For each of the four VAMCs we visited, we also interviewed VAMC and network officials regarding compliance with these requirements. Our findings on compliance are not generalizable beyond the purchases we reviewed. To ensure that the data we used to select purchases for review were sufficiently reliable for our purposes, we conducted a detailed data reliability assessment of the data that we used, which included checks for missing values and interviews with a VHA official knowledgeable about the data. We restricted these assessments, however, to the specific variables that were pertinent to our analyses. Our review revealed some inconsistencies and

⁷The FAR contains government-wide regulations and establishes uniform policies and procedures used by all executive branch federal agencies for their acquisitions. VA supplements the FAR with the VAAR to establish uniform policies and procedures for all VA acquisitions. The FAR and agency supplements are codified in title 48 of the Code of Federal Regulations. With respect to VA's and VHA's implementing policies for surgical implant purchases, we reviewed, for example, VA Handbook 7408.1, *Requesting Waivers From the Requirement to Use VA Federal Supply Schedules* (June 9, 2005); and VHA Directive 2009-062, *Management of Non-Biological Implantable Devices* (Nov. 23, 2009).

⁸The range in percentages is the result of large differences in the number of open market purchases at each VAMC.

errors in the data that were attributable to data entry errors and omissions. Overall, however, we found that all of the data were sufficiently reliable for selecting our purchases for review.

To examine VA and VHA's oversight of compliance with surgical implant purchasing requirements, we obtained and analyzed VA and VHA documentation on existing or planned monitoring activities, including audit plans and reports documenting deficiencies in VAMCs' purchasing of surgical implants; interviewed VA and VHA procurement and prosthetics officials and officials from the networks that oversee the four VAMCs we visited;⁹ and assessed VA and VHA's monitoring activities in the context of federal standards for internal control.¹⁰

We conducted this performance audit from April 2013 to January 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. See appendix I for more information on our scope and methodology, including additional information on the four VAMCs we visited, the purchases we reviewed, and the steps we took to assess data reliability.

Background

VHA provides health care services to veterans at VHA's 152 VAMCs and associated outpatient clinics. Such care can include providing surgical implants, where required—including biological implants, such as skin

⁹Each network has a prosthetics representative who is responsible for the day-to-day management of prosthetics purchasing at each VAMC.

¹⁰These standards provide an overall framework for establishing and maintaining internal control and for identifying and addressing major performance and management challenges and areas at greatest risk of fraud, waste, abuse, and mismanagement. For example, under the standards for internal control, monitoring should assess the quality of performance over time and ensure that the findings of audits and other reviews are promptly resolved. See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: Nov. 1, 1999) and its supplemental guide, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: Aug. 1, 2001).

grafts, and non-biological implants, such as cardiac pacemakers.¹¹ Surgeons and other clinicians at VAMCs determine veterans' needs for surgical implants and provide VAMC prosthetics purchasing staff with documentation showing which item will be implanted in the veteran or has already been implanted in the veteran (if the surgery has been completed).

The purchasing process used by VHA varies depending on the purchase price of the implant. For purchases under the FAR's micro-purchase threshold of \$3,000, prosthetics purchasing staff at VAMCs are responsible for ordering the implant that the clinician has requested for an upcoming surgery or replacing an implant in the VAMC's inventory after one has been used for a surgery, and subsequently documenting the purchase in VHA's prosthetics purchasing system.¹² This includes documenting information on the item purchased, the vendor, and the serial and lot numbers of the item implanted in the veteran. VHA has developed a new purchasing process for purchases above the FAR's micro-purchase threshold of \$3,000 but below the simplified acquisition threshold of \$150,000.¹³ This process requires prosthetics purchasing staff at VAMCs to work with contracting officers from VHA's NCOs, with the intention of achieving greater compliance with the FAR and the VAAR.¹⁴ VHA began implementing this process in fiscal year 2012, and VAMCs were required to implement it by the end of fiscal year 2013. As a first step under this new purchasing process, VAMC prosthetics purchasing staff begin assembling a contracting package in VHA's

¹¹Other common types of biological implants include tendons, bone chips and corneal implants, whereas other common types of non-biological implants include heart valves and stents.

¹²The prosthetics purchasing system is used to record the purchase of all prosthetics, including surgical implants.

¹³See 48 C.F.R. § 2.101 for threshold definitions and amounts. Purchases below the FAR's micro-purchase threshold of \$3,000 generally require less stringent documentation than purchases above the micro-purchase threshold. The FAR also sets forth the procedures applicable to purchases below the simplified acquisition threshold at 48 C.F.R. Part 13. These procedures are designed to promote efficiency and economy in contracting and to avoid unnecessary burdens for agencies and contractors. See 41 U.S.C. § 1901(a), (c); 48 C.F.R. § 13.002.

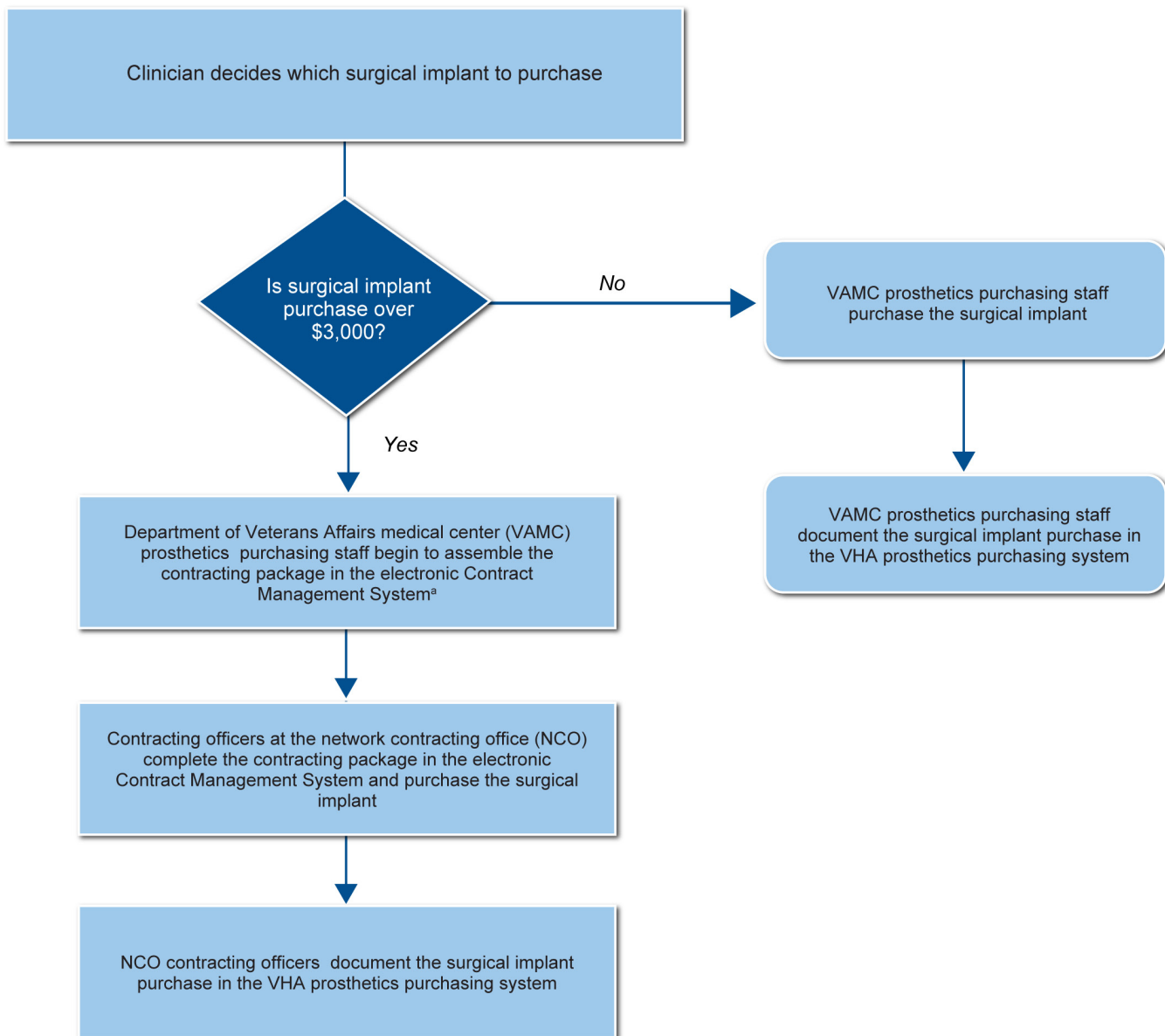
¹⁴Each contracting officer works within a NCO and is overseen by managers within that office who report to VHA's Procurement and Logistics Office. VHA had previously implemented this new purchasing process for other items, such as medical supplies.

electronic Contract Management System (eCMS),¹⁵ and are required to include specifications of the surgical implant requested by the clinician. Then, they submit this package to contracting officers at the corresponding NCOs who, in turn, are responsible for completing the contracting package for each purchase in eCMS. For each contracting package, NCO contracting officers have to enter over 100 data fields in eCMS. After completing the contracting package, NCO contracting officers are responsible for ordering the implant and documenting the purchase in the prosthetics purchasing system. VAMCs that had not yet implemented the new process were required to complete an abbreviated contracting package beginning in January 2013, outlined in a memorandum issued by VA's Office of Acquisition and Logistics, until they fully implemented the new purchasing process.¹⁶ (See fig. 1 for an overview of the new surgical implant purchasing process.)

¹⁵eCMS is a web-based system for recording contracting actions throughout VHA.

¹⁶Under the abbreviated process, the prosthetics purchasing staff completed an abbreviated contracting package, which they submitted to their respective NCO, and documented the surgical implant purchase in the VHA prosthetics purchasing system.

Figure 1: Veterans Health Administration's (VHA) New Processes for Purchasing Surgical Implants



Source: GAO review of VHA documentation.

^aAs of January 9, 2013, VAMCs that had not yet implemented the new contracting process for surgical implant purchases over \$3,000 were required to follow an abbreviated version of this process as outlined in a memorandum issued by VA's Office of Acquisition and Logistics. Under the abbreviated process, VAMC prosthetics purchasing staff completed an abbreviated contracting package, which they submitted to their respective NCO, and documented the surgical implant purchase in the VHA prosthetics purchasing system. VAMCs were required to fully implement the new contracting process by September 30, 2013.

When purchasing surgical implants, VAMCs are generally required to follow a purchasing hierarchy of preferred supply sources that favor competitive contracts, as specified in the VAAR.¹⁷ In order of preference, these competitive contracts are VA national committed-use contracts, Federal Supply Schedule (FSS) contracts, and regional or local contracts. The open market is the least preferred source, regardless of the cost of the implant. (See table 1 for a description of these types of contracts.)

Table 1: Overview of the Purchasing Hierarchy for Surgical Implants within the Veterans Health Administration (VHA)

| Order of priority | Type of contract | Description |
|-------------------|--|---|
| 1 | National committed-use contract | Negotiated by the National Acquisition Center—one of VA's contracting offices— these contracts typically establish a fixed price for several models of a certain type of surgical implant. ^a VHA commits to use the items included on these contracts throughout its healthcare system. As of September 2013, these contracts covered the following nine types of non-biological surgical implants: cardiac pacemakers and leads, implantable cardioverter-defibrillators, cardiac resynchronization treatment devices, remote monitoring devices, coronary stents, artificial hips, artificial knees, cochlear implants, and intraocular lenses. As of October 2013, these contracts only included non-biological implants. |
| 2 | Federal Supply Schedule (FSS) contract | Negotiated by the National Acquisition Center, these contracts are indefinite delivery-indefinite quantity contracts, which are awarded to multiple vendors for various types of surgical implants, both biological and non-biological. FSS contracts may include blanket purchase agreements, which allow VHA to purchase FSS items at prices that are further discounted from FSS prices, typically by agreeing to quantity requirements. Blanket purchasing agreements can be negotiated at the national, network, or VA medical center (VAMC) level. |
| 3 | Regional or local contract | Negotiated by VHA contracting officers, these contracts can cover a VAMC or network, and are indefinite delivery-indefinite quantity contracts. They do not cover items available on national committed-use contracts or FSS contracts. |
| 4 | Open market | Open market purchases are those that are not made through an existing contract. |

Source: GAO analysis of VAAR and VA policy document provisions.

^aVA officials noted that these contracts are generally multiple award, indefinite delivery-indefinite quantity contracts subject to ordering procedures under FAR 16.505.

¹⁷48 C.F.R. § 808.002(a).

Because open market purchases are the least preferred purchasing source in VA's purchasing hierarchy, VAMCs must request a waiver to purchase on the open market instead of using a higher-priority source of supply listed in the VAAR. As further stipulated by VA policy guidance, the waiver request must show that the clinical needs of the veteran cannot be met using a surgical implant available through a higher-priority contract—that is, a national committed-use contract, FSS contract, or regional or local contract. This requirement applies regardless of the cost of the implant.

Open market purchases of surgical implants above \$3,000 but below the FAR's simplified acquisition threshold of \$150,000 are subject to additional documentation requirements that are part of VHA's new contracting process, which VHA implemented to foster greater consistency in the application of relevant FAR and VAAR provisions. Under this process, the contracting package for such purchases must include, among other things, a written determination of price reasonableness and, if the purchase was made noncompetitively, a justification for other than full and open competition (JOFOC) citing the rationale for the sole-source award.

Clinicians Chose Surgical Implants Based Mainly on Patient Need, Their Clinical Expertise, and, To a Lesser Extent, Implant Availability on Purchasing Contracts

Clinicians at four VAMCs cited patient need and their clinical expertise in using available surgical implants as the most important factors influencing their decisions of which surgical implants to use. In addition, certain clinicians stated that the availability of committed use contracts also influenced their decisions, whereas the availability of FSS contracts generally did not.

Clinicians Cited Their Clinical Expertise and Patient Need as the Most Important Factors Influencing Their Decision of Which Surgical Implant to Use

Many clinicians we interviewed at the four selected VAMCs stated that the specific needs of the patient were one of the two main factors that influenced their decision of which surgical implant to purchase and use. Clinicians stated that even though different types of surgical implants may appear to be identical to the lay person, there may be differences that can affect patient outcome. For example, one clinician stated that a flexible stent available through only one vendor was necessary to meet the needs of a patient with arteries that were difficult to navigate.

Many of the clinicians we interviewed stated that the other main factor influencing their decision of which surgical implant to use was their clinical expertise, which they acquired through their training and clinical experience, review of relevant literature, and interaction with vendors who supply surgical implants:

- *Training and experience:* Many clinicians we interviewed stated that their experiences in using certain types of surgical implants during their medical training and/or as a practitioner significantly impacted their decision of which item to purchase and use. For example, one clinician stated that his knowledge of different types of surgical implants, including the different features of various implants, is the result of 30 years of training and experience.
- *Review of relevant literature:* Several clinicians stated that they regularly reviewed relevant literature to help identify the surgical implants with the greatest clinical efficacy. One clinician told us that he recently switched to a different type of skin graft because a review of the literature suggested that this item was more effective than the one that he had been using.
- *Interaction with vendors:* Several clinicians told us that they work closely with vendor representatives who supply surgical implants (for example, when implanting a pacemaker, a vendor representative may be involved in testing and programming the device). Further, some clinicians with whom we spoke said that their past experience working with a particular vendor, including whether they believe that the vendor representative is knowledgeable and reliable, helps drive their decision of which implant to use. For example, a clinician stated that the reliability of vendors was important in deciding which implant to use, since some implants are not stocked at a VAMC and it is important that implants are delivered by vendors in time for scheduled surgical procedures.

Implants' Availability on Certain Purchase Contracts Influenced Clinicians' Decisions

Clinicians who performed surgical procedures for which implants were available on a national committed-use contract stated that they typically used one of the implants available on this type of contract, unless the use of these items was not appropriate, for example, for certain complex clinical indications. As of September 2013, nine types of surgical implants—cardiac pacemakers and leads, implantable cardioverter-defibrillators, cardiac resynchronization treatment devices, remote monitoring devices, coronary stents, artificial hips, artificial knees, cochlear implants, and intraocular lenses—were available through national committed-use contracts. In developing national committed-use contracts, VHA solicits input from a group of VHA clinicians to determine which items to place on national committed-use contracts and to review them for clinical efficacy.¹⁸ Several different models of each type of implant are available on national committed-use contracts—for example, the contracts for pacemakers include models from three different vendors—thereby providing clinicians with a choice of which implant to use.

VHA has recognized the need to develop a greater number of these contracts for a variety of surgical implants, to better leverage its purchasing power and thereby pay lower prices for surgical implants. In 2011, VHA established a program management office for prosthetics to identify additional surgical implants that could be made available through these kinds of contracts and to facilitate the process of establishing and implementing them.¹⁹ As of October 2013, an official in VHA's program executive office told us the office has been focusing on renewing and re-soliciting existing contracts that are expiring. This official also told us that it had reviewed data on surgical implant purchases and had begun to identify items that are frequently used and high-cost. However, the official told us that it was unable to focus on developing additional national committed-use contracts because of staffing constraints, and did not have

¹⁸In developing national committed-use contracts, VHA establishes teams consisting of clinicians and other subject-matter experts who are familiar with the types of surgical implants that VHA is considering including on these contracts.

¹⁹In 2011, VHA established a program executive office, including six program management offices. Each of the six program management offices (surgery, medical, clinical support, ancillary, advanced systems, and prosthetics) is expected to collaborate with teams of clinicians and other stakeholders, who can provide insight on identifying certain medical devices for standardization. The program management offices also coordinate with VA's contracting offices, which are responsible for establishing national committed-use contracts for standardized items.

a plan or timeline for establishing new contracts. Without the establishment of national committed-use contracts for a greater number of surgical implants, VHA is not fully leveraging its purchasing power as one of the nation's largest health care systems.

While availability of implants via national committed-use contracts positively influenced their use by clinicians we interviewed, the availability of implants via FSS contracts rarely did so for a number of reasons. Clinicians at the four VAMCs we visited were often not aware of what surgical implants were available on an FSS contract, even though these contracts are preferred to open market purchases under the VAAR. For example, some of these clinicians mistakenly believed that a biological implant they were using was on an FSS contract, when in fact it was not. Clinicians at the four VAMCs we visited also lacked awareness of how to obtain information on which implants were available on an FSS contract. In addition, network prosthetics purchasing officials told us that it is difficult for both clinicians and prosthetics purchasing agents to use VHA's national database of FSS contracts to determine what specific items are available on an FSS contract. For example, the officials stated that very specific terms must be entered in the database's search field in order to obtain a useful list of items available on FSS contracts. Some clinicians stated that it would be helpful to have a user-friendly list of surgical implants available on FSS contracts, including the implant's attributes—such as its shelf life and approved clinical indication—for each surgical specialty. Clinicians at the four VAMCs we visited noted that such a list would allow them to consider FSS contract availability in making their decisions on which implant to use. We found that one VAMC we visited had begun developing a list of skin grafts available on FSS contracts, which included their attributes—such as whether the grafts had to be stored in a freezer—to help raise awareness of items available on FSS contract.

Some clinicians at the four VAMCs we visited also stated that if there is not sufficient data to support the clinical efficacy of an implant on an FSS contract, they would not feel comfortable using it. For example, at one VAMC, a clinician noted that a specific vendor who had an implant on an FSS contract questioned why the implant was not being purchased. The clinician asked for clinical efficacy data, which—according to the clinician—was never provided, and therefore the clinician decided not to use the item. Senior VHA prosthetics and contracting officials stated that clinicians are not involved in determining which surgical implants should be available on FSS contracts, and therefore the items available on FSS contracts may not always be those that clinicians prefer to use based on

their expertise and experience. Additionally, these officials expressed concern that an evaluation of the clinical efficacy of an item is not conducted in awarding FSS contracts. These officials further stated that VHA prefers to develop national committed-use contracts, for which a clinical efficacy evaluation is conducted. The director of a VHA clinical program that uses surgical implants further emphasized that clinician decisions on which implants to use should be based on proven clinical efficacy rather than inclusion on an FSS contract.

Selected VAMCs Did Not Fully Comply with VHA Requirements for Documenting Surgical Implant Purchases from the Open Market

We found that among the four VAMCs we visited: (1) none fully complied with requirements for obtaining waivers for open-market purchases of surgical implants; (2) none fully complied with additional requirements for documenting open-market purchases, which are part of VHA's new process for surgical implant purchases over \$3,000; and (3) three of the four did not comply with a requirement related to consignment agreements with surgical implant vendors.

Selected VAMCs Did Not Fully Comply with VHA Requirements for Obtaining Waivers for Open-Market Purchases of Surgical Implants

None of the four VAMCs we visited fully complied with VHA requirements for obtaining waivers for open-market purchases of surgical implants. We found that one VAMC partially complied with each requirement, while the others did not comply. Current VHA requirements applicable to the four VAMCs stipulate that

- all open-market purchases of non-biological implants require a waiver approved by the VAMC Chief of Staff—regardless of the purchase price—when a comparable item would have been available through a national committed-use contract, and
- all open-market purchases of biological implants require a waiver approved by VHA's Procurement and Logistics Office—regardless of the purchase price—when a decision is made to purchase an item from the open market rather than from an FSS contract.²⁰

²⁰These requirements are outlined in VHA policy documents.

On each of these waivers, VAMCs are required to document why the clinician chose not to use a surgical implant that is available on an existing, higher-priority contract—for example, because the clinician did not believe that the implant met a patient’s need or because the clinician had concerns about the quality of the items available on contract.

Specifically, compliance with these waiver requirements was as follows at the four VAMCs we visited:

- We found that only one of the four VAMCs we visited partially complied with the waiver requirement for open-market purchases of non-biological implants, when a comparable item was available through a national committed-use contract. At this VAMC, we found that waivers were obtained for 27 of the 30 purchases we reviewed; however, 20 of the 27 waivers were incomplete, as they lacked the approving signature from the VAMC Chief of Staff. A VAMC official told us that the Chief of Staff had granted certain clinicians the authority to approve their own waivers for open-market purchases; however, VHA prosthetics officials told us that the Chief of Staff may not delegate this authority and the VAMC was unable to provide documentation to support this claim. The other three VAMCs did not comply with the requirement, meaning that they did not obtain waivers for any of the purchases we reviewed.²¹ Two of these three VAMCs had a relatively high percentage of open-market purchases of non-biological implants in the first two quarters of fiscal year 2013 based on VHA data (33 percent and 35 percent, respectively) and one had a low percentage of such purchases (2 percent). Officials at two of the VAMCs told us that these waivers were not routinely obtained because they were focusing on other priorities instead, such as implementing VHA’s new process for surgical implant purchases over \$3,000. At the third VAMC, a prosthetics official told us that clinicians did not always fill out a waiver when asked to do so. Furthermore, because certain clinicians practice at the VAMC on a very limited

²¹At 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, in fact, on file and whether they were complete. At one of these VAMCs, we found that waivers were not on file, even though VHA data indicated that they were. VAMC officials told us that VAMC prosthetics purchasing staff mistakenly indicated that waivers were on file when making the purchases.

basis, the official said it is difficult to ensure that they are aware of the waiver requirement and comply with it.

- We found that only one of the four VAMCs we visited partially complied with the waiver requirement for biological implants when a decision is made to purchase an item from the open market rather than from an FSS contract, whereas the other three VAMCs did not comply.²² Officials from the three VAMCs that did not comply with the requirement told us that they did not obtain these waivers because they did not understand under what circumstances a waiver is required or were focusing on other priorities instead—such as implementing VHA’s new process for surgical implant purchases over \$3,000. The VAMC that partially complied with the waiver requirement for the purchases we reviewed had waivers on file, but the waivers did not include the required justification as to why a waiver was needed and did not have the required approval from VHA’s Procurement and Logistics Office. Prosthetics purchasing officials at this VAMC told us that they had only recently begun to establish compliance with this waiver requirement.

Without consistent and appropriate completion of waivers for open market purchases of surgical implants, VHA lacks information regarding why surgical implants were not being purchased from higher-priority sources such as a national committed use contract or an FSS contract. This information would help VHA determine whether clinicians raised concerns about the quality or efficacy of the items available through these existing contracts, which could help VHA improve future implant purchases, and could provide a basis for holding clinicians accountable for complying with VHA requirements and procurement best practices.

²²The VAMC that partially complied with this requirement was different than the one that partially complied with the waiver requirement for open-market purchases of non-biological implants, when a comparable item was available through a national committed-use contract. At each VAMC, we selected 20 to 30 purchases of biological implants which, 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.

Selected VAMCs Did Not Fully Comply with Additional VHA Requirements for Documenting Open-Market Purchases of Surgical Implants over \$3,000

None of the four VAMCs we visited fully complied with additional requirements for documenting open-market purchases of surgical implants below the FAR's simplified acquisition threshold but over \$3,000, which VHA established as part of its new purchasing process. However, all four were partially complying with the requirements. Beginning in fiscal year 2013, if a clinician requests a surgical implant over \$3,000 from the open market, the following are required:²³

- a statement affirming that the vendor's quoted price is fair and reasonable and the basis of this determination;²⁴ and
- a justification for other than full and open competition (JOFOC) that cites the legal authority for purchasing a surgical implant where the VAMC solicited only one source in making the open-market purchase.²⁵ Under VHA's new process, the JOFOC must cite one of two justifications applicable to sole-source purchases of surgical implants on the open market: (1) unusual and compelling urgency or

²³The beginning dates for completing these requirements varied by VAMC, depending on when they implemented VHA's new process for surgical implant purchases over \$3,000. We assessed compliance against the requirements in place at each of the four VAMCs we reviewed at the time the purchases were made.

²⁴The FAR provides several different methods for determining whether the vendor's price is fair and reasonable when using simplified acquisition procedures. Where possible, the contracting officer is to base price reasonableness on competitive quotations or offers. However, if only one response is received, the FAR requires a statement of price reasonableness in the contracting file, which may be based on such things as conducting market research, comparing the quoted price with the price of similar items in a related industry, or comparing the quoted price with prices found reasonable on a previous purchase, among other methods. See 48 C.F.R. § 13.106-3(a).

²⁵Although simplified acquisitions are exempt from the general requirement for full and open competition, contracting officers must promote competition to the maximum extent practicable when using simplified acquisition procedures and are to include a statement in the contracting file explaining the absence of competition when only one source is solicited. See 48 C.F.R. §§ 13.104, 13.106-1(b)(1), 13.106-3(b)(3)(i).

(2) VA's special authority under 38 U.S.C. § 8123 to acquire prosthetics without regard to other provision of law.²⁶

Depending on the VAMC, these documentation requirements were either completed by VAMC prosthetics purchasing staff or a contracting officer at the corresponding NCO.

Compliance with these requirements was as follows at the four VAMCs we visited:²⁷

- *Fair and reasonable price determination:* The fair and reasonable price determination was not on file for between 7 and 36 percent of the applicable purchases we reviewed at three of the four VAMCs. It was on file for all applicable purchases at the fourth VAMC. However, we found that the documentation on file did not provide reasonable assurance that the price was fair and reasonable for the majority of purchases we reviewed. We found multiple instances where the documentation indicated that the determination was based on "prior experience purchasing similar items" but did not cite any prior pricing information. Not citing any prior pricing information leaves open questions about the thoroughness of the analysis conducted to determine price reasonableness. We also identified cases where the contracting officer or prosthetics purchasing agent documented the price as "fair and reasonable" when it fell within a broad range of prices. For example, a contracting officer determined that about \$6,000 for a bone graft purchased from the open market was fair and reasonable because the sales prices for "similar" items was typically between \$3,000 and \$20,000.²⁸ VAMC and NCO officials we interviewed stated it is difficult to determine price reasonableness for

²⁶VHA's criteria for the unusual and compelling urgency exception is as follows: the surgical implant is not available for purchase on an existing contract and will be purchased on an open-market basis and (1) the delivery time does not meet the patient's medical needs and there is documentation to support the compelling special need or (2) a medical emergency exists and there is medical justification to support the need. VHA's criteria for justifying a sole-source purchase based on VA's special statutory authority under 38 U.S.C. § 8123 is as follows: the surgical implant is not available for purchase on an existing contract and will be purchased on an open-market basis because the patient's medical need cannot be met through the use of a required source of supply or service and there is medical documentation to support the need.

²⁷We reviewed between 15 and 28 purchases over \$3,000 at each VAMC we visited.

²⁸The FAR allows the fair and reasonable price determination to be based on a comparison with similar items in a related industry.

surgical implants, in part, because they need to be knowledgeable of the exact characteristics of the item in question in order to effectively evaluate price reasonableness. They also said they believed that as contracting officers gain more experience in purchasing surgical implants, they will learn to more effectively complete this documentation. Furthermore, an NCO official stated that specific guidance from VHA on how to effectively complete the fair and reasonable price determination for surgical implants would be helpful. Ineffective market research and determination of price reasonableness may result in VHA overpaying for surgical implants.

- *JOFOC*: During our review of selected open-market surgical implant purchases over \$3,000, we found two issues with respect to those purchases made on a sole-source basis for which a JOFOC was required under VHA's new purchasing process. First, the JOFOC was not on file for between 5 and 29 percent of the applicable purchases we reviewed at the four VAMCs we visited. Second, at three of the VAMCs we visited, we found that the officials responsible for completing the JOFOC selected the "unusual and compelling urgency" justification for each of the purchases we reviewed, even though some officials told us that they did not have a full understanding of which justifications applied. Specifically, we found the following:
 - Officials from two of these VAMCs told us that they were unclear about which justification to cite on the JOFOC for each purchase because they believed VHA guidance on this matter was insufficient. For example, one official responsible for completing the JOFOC stated that he did not understand the difference between the justifications and therefore picked the one that made the most sense to him.
 - Officials at another VAMC stated that they chose the "unusual and compelling urgency" justification because the contracting package for surgical implants is typically completed after the item has already been implanted and therefore this justification made the most sense to them. Furthermore, officials at this VAMC stated that a VHA draft directive on surgical implant purchasing discourages the use of VA's acquisition authority under 38 U.S.C. § 8123 to justify sole-source awards of surgical implants on the open market. Because they were discouraged from using this justification on the JOFOC, they tended to rely on the "unusual and compelling urgency" justification instead.

Moreover, while VHA requires each JOFOC to include sufficient facts and rationale to support why a specific justification was cited, only one of the four VAMCs fully provided this information for any of the purchases we reviewed. At two VAMCs, no rationale was provided for the justification selected. Furthermore, the JOFOCs at these two VAMCs were frequently missing required information, such as the contracting officer's signature, or were not completed until several months after the purchase. At the fourth VAMC, each JOFOC for the purchases we reviewed typically included a generic paragraph stating that the purchase was justified based on the determination of the clinician who requested the implant, regardless of which justification was cited. VAMC and NCO officials told us that clinicians' surgical implant purchase requests often do not contain sufficient information to support why the clinician was requesting the particular item. Because the JOFOCs we reviewed were often incomplete, VHA lacks assurance that support existed for the sole-source awards pursuant to VHA's policies at these four VAMCs.

As we discuss later, VA and VHA both identified more widespread areas of noncompliance (in the areas we describe above)—beyond the 4 VAMCs we visited—through oversight efforts they conducted at numerous VAMCs and NCOs nationwide. For example, VA's oversight identified extensive noncompliance, including inadequate fair and reasonable price determinations and missing or improperly completed JOFOCs.

VHA officials stated that they were familiar with the challenges that VAMCs and NCOs were experiencing with complying with the requirements of VHA's new process for surgical implant purchases over \$3,000 and acknowledged that some of these challenges stem from a lack of sufficient guidance for implementing this new process. To address these challenges, VHA officials stated that VHA has developed additional guidance to facilitate the purchase of these items. This guidance includes (1) revised JOFOC templates to help ensure that the correct purchasing justification is cited and that an appropriate rationale is provided for using each justification and (2) additional guidance on completing the fair and reasonable price determination, which, as of November 2013, had not yet been issued. Moreover, VHA contracting officials stated that VHA plans to provide training on the documentation of purchases over \$3,000; however, as of November 2013, this training had not yet been approved. In addition, VHA is developing a directive and associated standard operating procedure that outline the processes VAMCs and NCOs are expected to follow when completing contracting packages for surgical implant purchases over \$3,000, including a JOFOC in the event of a sole-

source purchase. As of November 2013, VHA was still in the process of providing its draft directive and standard operating procedure to stakeholders for review, and there are no established timelines for finalizing this directive and standard operating procedure, according to VHA officials. VHA officials stated that there had been disagreement between VHA prosthetics and contracting officials concerning the details of the directive and standard operating procedure—for example, which specific requirements would be the responsibility of VAMC prosthetics purchasing staff and which would be the responsibility of NCO contracting officers. According to VHA officials, these disagreements delayed the completion of these documents and disseminating them to VAMCs and NCOs.

VHA officials also told us that they are considering ways to streamline the documentation requirements for purchases over \$3,000 in response to concerns from VAMCs and NCOs about the resources required to complete a contracting package for each purchase and potential delays in making purchases for surgical implants, which could result in the postponement of needed medical procedures. For example, VHA officials stated that they are considering providing VAMC prosthetics purchasing staff with ordering officer delegations, which would allow them to purchase surgical implants from national committed-use contracts, without having to work with a contracting officer to complete a contracting package for such a purchase. They told us that this would free up contracting officers' time to work on documenting open market purchases and help ensure that these purchases are appropriately documented. However, VHA officials told us that they were still in the process of evaluating the feasibility of delegating ordering authority to prosthetics purchasing staff, including addressing technical challenges with the prosthetics purchasing system, which they said currently prevent VHA from effectively implementing this change. Again, no timelines have been established to complete streamlining efforts, according to VHA officials.

Three of Four VAMCs Did Not Comply with a VHA Requirement Pertaining to Consignment Agreements with Surgical Implant Vendors

Officials at three of the four VAMCs we visited told us that the VAMCs had purchasing agreements with open-market vendors to provide surgical implants to the VAMCs on consignment, but that these agreements were not always in compliance with a VHA requirement that consignment agreements be authorized by a VHA contracting officer.²⁹ Under a consignment agreement, the vendor maintains vendor-owned items at the VAMC, and the VAMC purchases only the items actually used. VAMC and network officials told us that clinicians likely made these unauthorized agreements with vendors to ensure that they had timely access to the surgical implants that they preferred to use. However, they could not tell us when these agreements had been established, who had authorized them, and what the terms of the agreements were. These officials told us that the unauthorized agreements with vendors have resulted in unauthorized commitments, vendors not being paid in a timely manner, and surgical implants not being tracked in the VAMCs' inventories.³⁰ Furthermore, because these unauthorized agreements covered surgical implants from the open market, and the purchase prices were not negotiated, the VAMCs may have overpaid for these items.

To address these unauthorized consignment agreements, officials at each of these VAMCs or the corresponding networks stated that they were in the process of establishing authorized consignment agreements which include an agreed-upon price and quantity for each surgical implant. Having authorized consignment agreements in place may be useful in instances where the requirement for a surgical implant is immediate and it is not possible to predetermine which of several types or models are required. Establishing such agreements involves determining the types of surgical implants that clinicians need to have available on a consignment basis and obtaining a contracting officer's authorization for the VAMC to enter a consignment agreement with the vendors. At the time of our review, VHA was developing a standard operating procedure

²⁹See VHA Directive 2009-062, *Management of Non-Biological Implantable Devices* (Nov. 23, 2009). Officials responsible for surgical implant purchasing at the fourth VAMC told us that they did not have any unauthorized consignment agreements in place.

³⁰Unauthorized commitments refer to situations where a contract is entered into by someone other than an authorized contracting officer. We previously reported that tracking items used for patient care in VAMC inventories is important to help respond to a manufacturer or Food and Drug Administration recall of these items. See GAO, *VA Health Care: Weaknesses in Policies and Oversight Governing Medical Supplies and Equipment Pose Risks to Veterans' Safety*, [GAO-11-391](#) (Washington, D.C.: May 3, 2011).

to assist VAMCs and NCOs in developing authorized consignment agreements, however, as of November 2013 they were unsure as to when it would be finalized and rolled out to the VAMCs.

VA and VHA Did Not Ensure that Corrective Actions Were Taken when Noncompliance with Surgical Implant Purchasing Requirements Was Identified

As a result of their oversight efforts, VA and VHA found noncompliance with surgical implant purchasing requirements, but did not ensure that NCOs or VAMCs took corrective action. Furthermore, VHA assesses how each VAMC is performing on key aspects of the surgical implant purchasing process, but it did not ensure that VAMCs took corrective action to address deficiencies identified or require networks to do so.

VA and VHA Found Noncompliance with Requirements for Surgical Implant Purchases over \$3,000 but Neither Took Steps to Ensure that Corrective Actions Were Taken

Oversight of VAMCs' and NCOs' compliance with VHA's new process for surgical implant purchasing over \$3,000 includes efforts by both VA's Office of Acquisition and Logistics and VHA's Office of Procurement and Logistics.³¹ However, this oversight was not fully effective because neither VA nor VHA ensure that corrective action is taken to address noncompliance.

Recent VA and VHA oversight activities that identified significant noncompliance issues included the following:

- *VA oversight:* In February 2013, VA's Office of Acquisition and Logistics began assessing compliance with its January 9, 2013, memorandum, which required VAMCs that had not fully implemented VHA's new process for surgical implant purchasing over \$3,000 to complete an abbreviated contracting package, including a fair and reasonable price determination and, if applicable, a JOFOC. This oversight effort, which examined several hundred purchases between February 2013 and August 2013, identified extensive noncompliance,

³¹This oversight assessed compliance with prosthetics purchases over \$3,000, not just surgical implants.

including inadequate fair and reasonable price determinations and missing or improperly completed JOFOCs, which were similar to the issues we identified in our assessment.

- *VHA oversight:* In April 2013, VHA began conducting oversight of surgical implant purchases over \$3,000 for the seven NCOs (and the VAMCs associated with those NCOs) that had fully implemented the new process.³² Additional oversight is planned for fiscal year 2014 for all NCOs. An audit team from VHA's Procurement and Logistics Office is using a checklist consisting of nine questions, which assess various requirements of the purchasing process, such as whether the fair and reasonable price determination and a JOFOC, if applicable, is on file for each purchase. VHA's oversight identified noncompliance including various missing or incomplete documentation in the contracting packages for surgical implant purchases over \$3,000.

While VA and VHA both conducted oversight and identified instances of noncompliance, they did not ensure that corrective action was taken. Consistent with the federal internal control standard for monitoring, which states that actions should be taken promptly in response to findings or recommendations, VA and VHA should have taken steps to ensure that noncompliance is addressed in a timely manner.³³ A senior official from VHA's Procurement and Logistics Office told us that VA's Office of Acquisition and Logistics did not provide VHA with information on the VAMCs at which noncompliance was identified, which—according to the official—would have allowed VHA to take steps to address noncompliance at the appropriate VAMCs. The official also told us that VHA's oversight is largely intended to be consultative in nature and that VHA's Procurement and Logistics Office is not sufficiently staffed to ensure that corrective action is taken. Therefore, while VHA asked NCOs to correct areas of noncompliance, VHA did not require NCOs to document how they addressed, or plan to address, noncompliance identified in VHA oversight activities. Because neither VA nor VHA have taken steps to ensure that corrective actions are taken to address VAMC and NCO noncompliance, they lack assurance that this noncompliance is being appropriately addressed.

³²VHA officials told us that VHA also conducted oversight in May 2012 and June 2012 of the three NCOs that had piloted the new purchasing process.

³³See [GAO/AIMD-00-21.3.1](#) and [GAO-01-1008G](#).

VHA Assesses VAMCs' Performance on Metrics Established for Surgical Implant Purchasing, but Has Not Required Networks to Ensure that VAMCs Address Deficiencies Identified

VHA assesses how each VAMC within VHA's 21 networks performs on metrics established for surgical implant purchasing, and provides the results of its assessments to the prosthetics representative at each network.³⁴ According to VHA prosthetics officials, VHA's assessments cover the following metrics:

- 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;
- the extent to which VAMCs entered the serial number and lot number for each surgical implant purchase;
- the timeliness of each surgical implant purchase—that is, the time from which a clinician requests a surgical implant to the time the item is purchased;
- the extent to which clinicians' purchase requests for surgical implants have been fulfilled; and
- the extent to which amounts obligated for surgical implant purchases have been recorded in the prosthetics purchasing system.

Network prosthetics representatives at two of the four networks we visited told us that they regularly monitored the results from VHA's assessments and took steps to ensure that VAMCs address deficiencies VHA identified, such as correcting data entry errors. At the other two VAMCs, network prosthetics representatives did not take such steps. In both networks that did not ensure that VAMCs address deficiencies, VHA's metrics identified a relatively high rate of noncompliance with surgical implant purchases from national committed-use contracts (28 percent at one network and 13 percent at the other network in the first three quarters of fiscal year 2013). At one of these networks, this noncompliance included a high percentage of purchases missing serial numbers or lot numbers (16 percent in the first three quarters of fiscal year 2013).³⁵ The

³⁴The network prosthetic representative in each of VHA's 21 networks is responsible for supporting VHA in managing and overseeing VAMCs' prosthetics service. VHA's metrics cover all prosthetics, not just surgical implants.

³⁵VA has been developing a new system—called Veterans Implant Tracking and Alert System (VITAS)—for tracking and retrieving identifying information—including the lot and serial number—of surgical implants placed in patients. See appendix II for more information on VITAS.

failure to address deficiencies uncovered through VHA's assessments may lead to higher costs for VHA and may have patient safety implications. For example, not recording the serial number or lot number for a surgical implant makes it difficult to systematically determine which veteran received an implant subject to a subsequent manufacturer or Food and Drug Administration recall.

As of November 2013, VHA did not have a policy governing how deficiencies identified through these assessments should be addressed. Accordingly, VHA officials told us that they have not required VAMCs to address deficiencies—i.e., if VAMCs do not meet an established threshold for each metric—nor did they require network prosthetics representatives to do so. Consistent with the federal internal control for monitoring, VHA or networks should establish a process to ensure that deficiencies are addressed. According to VHA officials, the directive on surgical implant purchasing that VHA is developing will require network prosthetics representatives to review each metric and ensure that deficiencies are addressed.

Conclusions

To its credit, VHA has established national committed-use contracts for a number of surgical implants, which can help VHA effectively leverage its purchasing power. We found that an implant's availability on this type of contract positively influenced clinicians' decisions to use that implant, but these types of contracts are only available for a limited number of surgical implants. Establishing national committed-use contracts for a greater number of commonly used surgical implants could help reduce the number of open-market purchases of these items and ultimately reduce the costs for VA. Furthermore, steps could be taken to improve clinicians' awareness of high quality surgical implants available on FSS contracts, which may also lead to a further reduction in open-market purchases.

While VHA has requirements in place to document surgical implant purchases from the open market, selected VAMCs did not fully comply with these requirements and VA and VHA's own oversight found similar issues at other VAMCs nationwide. Greater compliance with these requirements would provide VHA with information needed to determine why VAMCs are purchasing surgical implants from the open market; it would also help provide assurance that VHA is paying a fair and reasonable price for surgical implants.

VA's and VHA's oversight of compliance with surgical implant purchasing requirements does not ensure that corrective action is taken to address identified noncompliance, which could lead to potentially serious issues remaining unaddressed. For example, while VHA identified that at one VAMC a high number of serial numbers for surgical implants were not recorded—as required—in the prosthetics purchasing system, VHA did not ensure that this problem was addressed, resulting in potential patient safety issues remaining unresolved. Providing effective oversight of surgical implant purchasing, which includes ensuring that noncompliance is addressed, would help VA and VHA improve compliance with its applicable requirements, while potentially lowering costs for surgical implants, and improving patient safety.

Recommendations for Executive Action

To expand the volume of surgical implants purchased from existing, higher-priority contracts and to improve compliance and oversight related to purchasing requirements, we recommend that the Secretary of the Department of Veterans Affairs take the following five actions:

- Create a plan that includes timelines for evaluating the benefits of developing additional national committed-use contracts for surgical implants and establishing these contracts.
- Explore options to increase clinicians' awareness of high quality surgical implants available on FSS contracts, including developing a user-friendly list for VAMC clinicians of surgical implants available on FSS contracts for each surgical specialty.
- Re-emphasize to VAMCs that waivers must be completed for open-market purchases of surgical implants, provide clear guidance to VAMCs on when and how to complete these waivers, and establish internal controls to ensure VAMCs' compliance with waiver requirements.
- Provide additional training to VAMCs and NCOs on how to properly document open-market purchases of surgical implants over \$3,000, including those awarded on a sole-source basis.
- Enhance information sharing on noncompliance between VA and VHA and 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.

Agency Comments

VA provided written comments on a draft of this report, which we have reprinted in appendix III. In its comments, VA generally agreed with our conclusions, concurred with our five recommendations, and described the department's plans for implementing each of our recommendations. For example, VA will create a plan for evaluating the benefits of developing additional national committed-use contracts for surgical implants; develop and disseminate a list of surgical implants available on FSS contracts; emphasize the FSS waiver process through webinar trainings and standard operating procedures guidance; develop a checklist for proper documentation of open-market surgical implant purchases over \$3,000; and require documentation of measures taken to address noncompliance identified in audits. VA also provided a technical comment, which was incorporated as appropriate.

We are sending copies of this report to appropriate congressional committees and the Secretary of Veterans Affairs. The report is also available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or williamsonr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.



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Director, Health Care

Appendix I: Scope and Methodology

To conduct our work, we visited Department of Veterans Affairs (VA) medical centers (VAMC) in four locations: Indianapolis, Indiana; Los Angeles, California; New York, New York; and Seattle, Washington. We selected these four VAMCs because they are all classified by the Veterans Health Administration (VHA) as surgically complex facilities, serve large veteran populations and are located in different regional networks (See table 2).¹

| Table 2: Characteristics of VA medical centers (VAMC) Selected for Site Visits | | |
|--|---------------------------------|----------------|
| VAMC location | Patient population served, 2011 | Network number |
| Indianapolis, Indiana | 59,372 | 11 |
| Los Angeles, California | 84,436 | 22 |
| New York, New York ^a | 75,860 ^a | 3 |
| Seattle, Washington | 87,483 | 20 |

Source: GAO analysis of VHA data.

^aWe visited both the Bronx and New York Harbor VAMCs. We are treating these locations as one site visit, because, due to their close proximity, certain clinical specialties are only represented at one location. We reported the total patient population for both locations. In 2011, the Bronx VAMC served 24,625 patients and the New York Harbor VAMC served 51,235 patients.

To examine the factors clinicians consider when choosing which surgical implant to use, when multiple, similar types of implants are available, at each of the four VAMCs, we interviewed at least one clinician from each of the following six clinical specialties that typically use surgical implants: cardiology or cardiac surgery; general surgery; orthopedic surgery; neurosurgery; podiatry; and vascular surgery. In total, we interviewed 28 clinicians. During each interview, we discussed the factors that affected clinicians’ surgical implant purchase decisions and their knowledge of surgical implants available on national committed-use contracts and federal supply schedule (FSS) contracts. In addition, we interviewed staff involved in managing surgical implants at the VAMCs, such as the operating room nurse manager, surgical implant coordinator, or sterile processing service technician.

To assess compliance at the four selected VAMCs with pertinent VHA requirements for documenting surgical implant purchases from the open market, we first identified the applicable requirements. To do so, we

¹VAMCs are categorized according to complexity level, which is determined on the basis of characteristics of the patient population, clinical services offered, and other factors.

reviewed VA's statutory authority to acquire prosthetics—including surgical implants, applicable federal regulations—including the Federal Acquisition Regulation (FAR) and VA Acquisition Regulation (VAAR) and implementing guidance issued by VA and VHA with respect to surgical implant purchasing.² To learn more about VA's and VHA's surgical implant purchasing processes and, in particular, surgical implant purchases from the open market, we also interviewed procurement and prosthetics officials at VA and VHA. For purposes of our review, we selected pertinent VHA requirements for documenting surgical implant purchases from the open market. We assessed compliance with these requirements at the four selected VAMCs as follows:

- To assess compliance with the requirement that a waiver be obtained and approved by the VAMC Chief of Staff for open-market purchases of non-biological implants, for which a comparable product is available on a national committed-use contract, we selected 20 purchases at one VAMC and 30 purchases at another VAMC made between October 2012 and March 2013 for which data from VHA's National Prosthetics Patient Database (NPPD) indicated that such a waiver was obtained.³ These selected purchases represented about 35 and 80 percent, respectively, of all applicable purchases at each VAMC during this time period. We subsequently reviewed whether those waivers were, in fact, on file at the two VAMCs and whether they were complete. We selected the purchases for our review to obtain a diverse selection of purchases from different vendors.⁴ At the two

²The FAR contains government-wide regulations and establishes uniform policies and procedures used by all executive branch federal agencies for their acquisitions. VA supplements the FAR with the VAAR to establish uniform policies and procedures for all VA acquisitions. The FAR and agency supplements are codified in title 48 of the Code of Federal Regulations. With respect to VA's and VHA's implementing policies for surgical implant purchases, we reviewed, for example, VA Handbook 7408.1, *Requesting Waivers From the Requirement to Use VA Federal Supply Schedules* (June 9, 2005); and VHA Directive 2009-062, *Management of Non-Biological Implantable Devices* (Nov. 23, 2009).

³We selected a maximum of 5 purchases per month, between October 2012 and March 2013.

⁴The NPPD is a database containing information on each surgical implant purchase that is recorded by prosthetics purchasing agents and contracting officers in each VAMC's prosthetics purchasing system. The prosthetics purchasing system allows staff to indicate whether a waiver is on file for an open-market purchase of a non-biological implant for which a comparable item is available on a national committed-use contract. We reviewed 20 and 30 non-biological implant purchases at the two VAMCs, which ranged in price from \$1,496 to \$22,500 and included various types of non-biological implants, such as artificial joints and cardiac pacemakers.

other VAMCs we visited, the NPPD data indicated that no waivers had been obtained, even though there were open-market purchases of non-biological implants, for which an alternative product was available on a national committed-use contract. At these two VAMCs, we interviewed VAMC and network prosthetics staff about why the waivers had not been obtained.

- To assess compliance with the requirement that a waiver be obtained when a decision is made to purchase a biological implant from the open market rather than from a Federal Supply Schedule (FSS) contract, at each VAMC, we selected 20 to 30 purchases of biological implants made between October 2012 and March 2013 which, based on NPPD data, appeared to have been purchased from the open market because the NPPD data did not indicate the purchase was associated with a contract, and assessed whether a waiver was on file for those purchases, and if so, whether the waiver was complete.⁵ We selected the purchases for our review to obtain a diverse selection of purchases from different vendors.⁶ We selected 110 purchases in total representing from about 9 percent to about 83 percent of all applicable purchases meeting our selection criteria at each VAMC during this time period.⁷
- To assess compliance with VHA's requirements for open-market surgical implant purchases over \$3,000, including (1) a statement affirming that the vendor's quoted price is fair and reasonable and (2) a justification for other than full and open competition (JOFOC) in the case of a sole-source award, we reviewed a selection of open-market purchases over \$3,000 from each VAMC to determine whether the required documentation was on file and whether it was complete. At three of the four VAMCs, which had implemented VHA's new

⁵We selected a maximum of 5 purchases per month, between October 2012 and March 2013.

⁶We identified open-market purchases in the NPPD by searching for purchases without a contract number. Prosthetics purchasing agents and contracting officers enter the contract number in the prosthetics purchasing system for any surgical implant purchase made from a contracted source. At one VAMC, only 20 purchases met our selection criteria, and we reviewed all 20 of these purchases. At the other 3 VAMCs we selected 30 purchases each. The biological implant purchases we reviewed at the four VAMCs ranged in price from \$66 to \$11,473 and included various types of biological implants, such as bone grafts and cornea replacements.

⁷The range in percentages is the result of large differences in the number of open market purchases of biological implants at each VAMC.

process for surgical implant purchases over \$3,000 by the beginning of fiscal year 2013, we selected 30 purchases made between October 2012 and March 2013 which, based on NPPD data, appeared to have been purchased from the open market because the NPPD data did not indicate that the purchase was associated with a contract.⁸ At the fourth VAMC, we selected 15 purchases made between January 9, 2013, and March 31, 2013, which, based on NPPD data, appeared to have been purchased from the open market, because this VAMC had not yet implemented VHA's new process for surgical implant purchasing over \$3,000 and therefore was not required to complete the VHA requirements until January 9, 2013. We selected the purchases for our review to obtain a diverse selection of purchases from different vendors. We selected 97 purchases in total representing from about 6 percent to about 8 percent of all applicable purchases at each VAMC during this time period.

To ensure that the NPPD data we used to select purchases for review were sufficiently reliable for our purposes, we conducted a data reliability assessment of the data that we used, which included checks for missing values and interviews with a VHA official knowledgeable about the data. We restricted these assessments, however, to the specific variables that were pertinent to our analyses. Our review revealed some inconsistencies and errors in the data that were attributable to data entry errors and omissions. Overall, however, we found that all of the data were sufficiently reliable for selecting our purchases for review. We cannot generalize our findings on compliance beyond the purchases we reviewed.

We also reviewed documentation and interviewed VAMC and network officials at the four VAMCs we visited regarding compliance with these requirements.

⁸We selected a maximum of 5 purchases per month, between October 2012 and March 2013. We identified open-market purchases in the NPPD data by searching for purchases without a contract number. Based on the documentation we reviewed at each VAMC, we found that some of the purchases we selected were actually made from a contracted-source, but that the contract number was not entered, and we excluded these purchases from our review. After excluding these purchases, we reviewed between 15 and 28 purchases at each of the VAMCs we visited. These purchases ranged in price from \$3,019 to \$20,310 and included various types of surgical implants such as stents and heart valves.

To examine VA and VHA's oversight of compliance with surgical implant purchasing requirements, we obtained and analyzed VA and VHA documentation on existing or planned monitoring activities, including audit plans and reports documenting deficiencies in VAMCs' purchasing of surgical implants; interviewed VA and VHA procurement and prosthetics officials; and assessed VA and VHA's monitoring activities in the context of federal standards for internal control.⁹ The internal control standard for monitoring refers to an agency's ability to assure that ongoing review and supervision activities are conducted, with the scope and frequency determined by the level of risk; deficiencies are communicated to at least one higher level of management; and actions are taken in response to findings or recommendations within established timelines.

We conducted this performance audit from April 2013 to January 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁹These standards provide an overall framework for establishing and maintaining internal control and for identifying and addressing major performance and management challenges and areas at greatest risk of fraud, waste, abuse, and mismanagement. See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: Nov. 1, 1999) and its supplemental guide, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: Aug. 1, 2001).

Appendix II: Veterans Implant Tracking and Alert System

According to Veterans Health Administration (VHA) officials, in 2008, the Department of Veterans Affairs' (VA) 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 shortcomings in VHA's existing ability to track surgical implants, which may limit VHA's ability to identify and locate patients who received an implant in the event of a manufacturer or Food and Drug Administration recall. According to VHA, these shortcomings include the following:

- As we noted previously in this report, the lot number and serial number of items implanted in patients is not always entered into the prosthetics purchasing system, 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 not 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.¹

According to VA and VHA officials involved in the development of VITAS, the development of this system was suspended as of the end of fiscal year 2012 due to data-reliability and interoperability challenges. As of December 2013, VA and VHA had not decided whether to resume the development of VITAS.

¹According 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.

Appendix III: Comments from the Department of Veterans Affairs



DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

December 23, 2013

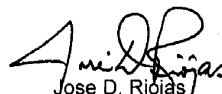
Mr. Randall Williamson
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Williamson:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, ***"VA SURGICAL IMPLANTS: Purchase Requirements Were Not Always Followed at Selected Medical Centers and Oversight Needs Improvement"*** (GAO-14-146). VA generally agrees with GAO's conclusions and concurs with GAO's recommendations to the Department.

The enclosure specifically addresses GAO's five recommendations in the draft report and provides an action plan for each. VA appreciates the opportunity to comment on your draft report.

Sincerely,


Jose D. Riojas
Chief of Staff

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA SURGICAL IMPLANTS: Purchase Requirements Were Not Always Followed
at Selected Medical Centers and Oversight Needs Improvement”***
(GAO-14-146)

GAO Recommendation: To expand the volume of surgical implants purchased from existing, higher-priority contracts and to improve compliance and oversight related to purchasing requirements, we recommend that the Secretary of the Department of Veterans Affairs direct the Undersecretary for Health to take the following actions:

Recommendation 1: Create a plan that includes timelines for evaluating the benefits of developing additional national committed-use contracts for surgical implants and establishing these contracts.

VA Comment: Concur. The Veterans Health Administration (VHA) Procurement and Logistics Office (PLO) will create a plan for evaluating the benefits of developing additional national committed-use contracts for surgical implants. The plan will include a timeline for conducting the benefit analysis. If VHA determines additional national committed-use contracts for surgical implants would be beneficial, the Office of Acquisitions, Logistics, and Construction (OALC) will create a plan for establishing such national contracts and a timeline for executing the plan. Target completion date: June 30, 2014.

Recommendation 2: Explore options to increase clinicians' awareness of high quality surgical implants available on FSS contracts, including developing a user-friendly list for VAMC clinicians of surgical implants available on FSS contracts for each surgical specialty.

VA Comment: Concur. VHA's Prosthetics and Rehabilitation Services Office in collaboration with VHA's PLO will develop a list of surgical implants available on Federal Supply Schedule (FSS) contracts, and VHA's National Surgical Office will disseminate the list to the field. Target completion date: July 30, 2014.

Recommendation 3: Re-emphasize to VAMCs that waivers must be completed for open-market purchases of surgical implants, provide clear guidance to VAMCs on when and how to complete these waivers and establish internal controls to ensure VAMCs' compliance with waiver requirements.

VA Comment: Concur. VHA's PLO will emphasize the FSS waiver process to VA medical centers (VAMC), Network Contracting Offices (NCO), and Chief Logistic Officers, through a series of Webinar trainings. The process for completing FSS waivers will be conveyed through trainings and standard operating procedures guidance. Also, during the training sessions, VHA's PLO will reiterate use of the Federal Supply Schedule Request for Waiver Checklist (VA Form 0753A), to ensure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***"VA SURGICAL IMPLANTS: Purchase Requirements Were Not Always Followed
at Selected Medical Centers and Oversight Needs Improvement"***
(GAO-14-146)

VAMCs adherence to established controls and compliance with waiver requirements.
Target completion date: May 30, 2014

Recommendation 4: Provide additional training to VAMCs and NCOs on how to properly document open-market purchases of surgical implants over \$3,000, including those awarded on a sole-source basis.

VA Comment: Concur. VHA's PLO will develop a checklist for VAMCs and NCOs to use on how to properly document open-market purchases of surgical implants over \$3,000 including those awarded on a sole-source basis. Target completion date: June 30, 2014.

Recommendation 5: Enhance information sharing on noncompliance between VA and VHA and 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.

VA Comment: Concur. VHA's Procurement Audit Office will share all audit results with OALC and ensure the audit includes a requirement for the NCOs to document the measures they are taking to address noncompliance and report their progress to the service area organizations. VHA prosthetic audits will be conducted monthly or bi-monthly depending upon staffing availability during fiscal year 2014. Target completion date: November 30, 2014.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Ashley Dixon; Cathleen Hamann; Jennifer Whitworth; and Michael Zose made key contributions to this report.

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