



# **Department of Veterans Affairs Office of Inspector General**

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## **Audit of the Acquisition and Management of Selected Surgical Device Implants**

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## **Executive Summary**

### **Introduction**

The Office of Inspector General (OIG) conducted an audit to assess the effectiveness of the Veterans Health Administration's (VHA) acquisition and management of selected surgical device implants (SDI). The audit assessed whether VHA facilities obtained the best prices for SDI purchased through local contracts and the open market as well as the effectiveness of SDI management controls for inventories, patient data, and implant recalls.

VHA's Prosthetics and Sensory Aids Service (PSAS) provides a full range of prosthetics and sensory aids services to veterans, including durable medical equipment, artificial limbs, sensory aids, and SDI. SDI are medical devices that are implanted in the body to replace and act as missing or defective biological structures. To monitor the procurement and utilization of orthotic, prosthetic, and sensory devices for VA patients, PSAS maintains information such as implant type, device cost, quantity purchased, and manufacturer in the National Prosthetics Patient Database (NPPD). In fiscal year (FY) 2006, PSAS spent \$340 million (31 percent) of its \$1.1 billion in funding on SDI. As of September 2007, PSAS estimated that SDI spending will exceed \$562 million (46 percent) of its \$1.23 billion budget.

In accordance with the purchasing hierarchy established by the Secretary's Procurement Reform Task Force in May 2002, VA purchases the majority of its SDI under national contracts or Blanket Purchase Agreements (BPAs) to leverage its buying power. However, VHA facilities purchase selected SDI—aortic valves, coronary stents, and thoracic grafts—through local contracts and the open market. For the 12-month period, July 2005 through June 2006, the NPPD reported that VHA facilities purchased 28,830 aortic valves, coronary stents, and thoracic grafts at a cost of about \$71.3 million.

### **Results**

VHA could reduce its procurement costs for aortic valves, coronary stents, and thoracic grafts and should strengthen key SDI management controls in the areas of inventory, patient privacy, and recalls. Based on the purchasing hierarchy established by VA's Procurement Reform Task Force in May 2002, national contracts and BPAs are the preferred methods for procuring SDI because they allow VA to leverage its buying power. (A BPA is a method of acquiring products at discounted prices, typically by agreeing to quantity or market share purchase requirements.) The National Acquisition Center (NAC) in VA's Office of Acquisition and Materiel Management and PSAS are responsible for determining the most economical method to supply centrally managed items, including SDI. However, the establishment of national contracts and BPAs for aortic valves, coronary stents, and thoracic grafts has not been a high priority.

Consequently, VHA facilities use local contracts and the open market to purchase these selected SDI.

Our survey of VHA facilities that purchased the selected SDI disclosed that implant prices varied significantly among VHA facilities due to factors such as the experience and negotiation skills of the contracting staff, the volume of purchases, and the relationship between the manufacturer and VHA facility. Although PSAS uses NPPD data to monitor the utilization and procurement of SDI, it did not detect these price differences because VHA facilities did not use standardized naming conventions when they identified purchased devices in the NPPD. Consequently, PSAS lacked the device-specific information needed to compare procurement data across the different VHA facilities.

If VHA leveraged its buying power and established national contracts and BPAs for these devices, we believe that it could negotiate national prices at least equal to the lowest prices identified during our survey. Based on our survey results and SDI purchases made during the review period, the use of national contracts and BPAs instead of local contracts and open market purchases could reduce VHA's costs for these selected SDI by as much as \$4.34 million annually or \$21.7 million over 5 years.

After the VHA facilities procured the SDI, we found that they lacked inventory controls needed to effectively manage and account for the devices. VHA facility staff did not conduct physical inventories and use VHA's Prosthetics Inventory Package (PIP) to maintain perpetual inventory records for SDI as required by VHA policy. As a result, staff lacked reliable information regarding SDI stock stored in various locations at the VHA facilities and could not effectively manage purchased stock to prevent implants from expiring. Inventories of VHA-purchased aortic valves, coronary stents, and thoracic grafts conducted during our site visits identified expired devices and devices set to expire unused within 6 months of our visit based on the VHA facilities' usage rates. Furthermore, the lack of inventory records prevented us from identifying the amount of stock that had expired prior to our onsite visits and its disposition.

VHA facility staff also routinely disclosed more private medical information and sensitive personal data to implant manufacturers than the manufacturers needed. VHA's Privacy Program requires Privacy Officers to ensure compliance with privacy statutes. In addition, VHA's Privacy Program and the Health Insurance Portability and Accountability Act (HIPAA) require VHA staff to limit the disclosure of patient information to the minimum amount necessary. However, seven (88 percent) of eight VHA facilities we reviewed had no procedures in place to identify specific Food and Drug Administration (FDA) and SDI manufacturers' information requirements and ensure the release of only the minimum amount of relevant patient information. Consequently, staff at the seven VHA facilities often provided SDI manufacturers patients' medical information and personal data that the manufacturer did not need to

meet FDA requirements, thus placing the patients at risk for identity theft or other misuse of information for commercial advantage, personal gain, or malicious harm.

Finally, some VHA facilities lacked effective SDI recall procedures to ensure that all patients with recalled SDI received prompt follow-up care. VHA policy requires its facilities to have procedures in place to address, review, and take action on defective medical device and medical product recalls. These requirements include maintenance of a system of records to document resolution of the recalls and notification of any additional parties needed to assist in implementation of the recalls. Despite these requirements, one (25 percent) of the four VHA facilities reviewed did not have an effective system in place to identify and track cardiology patients subject to SDI recalls and to document actions taken to resolve the recalls. Staff at this VHA facility believed the affiliated university providing the follow-up care for the VHA facility's VA patients was responsible for resolving the recalls. Consequently, the VHA facility did not take needed actions to follow up on its cardiology patients with recalled SDI, and our audit confirmed that at least two patients did not receive timely follow-up care. VHA officials reported other instances where its facilities had problems recalling other types of SDI when we conducted our follow-up for these two patients. Hence, we believe a VHA initiative to develop a national implant registry will significantly strengthen local and national VHA SDI recall processes.

## **Conclusion**

VHA needs to use national contracts and BPAs to reduce its SDI costs. VHA also needs to strengthen management controls related to SDI inventory, patient privacy, and recalls. Our audit found that VHA could reduce its costs for aortic valves, coronary stents, and thoracic grafts if it procured them through national contracts and BPAs instead of local contracts and the open market. The standardization of NPPD data would strengthen PSAS's monitoring of SDI procurement and utilization. Moreover, VHA facilities need to implement SDI inventory controls before staff can adequately account for purchased devices and manage stock levels to reduce losses due to expired devices. Finally, VHA also needs to strengthen SDI patient safeguards to prevent the unnecessary release of sensitive patient data and to ensure VA patients affected by recalls receive timely follow-up care.

## **Recommendations**

1. We recommended that the Under Secretary for Health, within a year, evaluates VHA's aortic valve, coronary stent, and thoracic graft purchases; studies the feasibility of establishing national contracts and BPAs; and where indicated, initiates national contracts and BPAs.

2. We recommended that the Under Secretary for Health establish management controls to standardize NPPD data used to monitor SDI procurement and utilization.
3. We recommended that the Under Secretary for Health conduct physical inventories of SDI and use PIP to track inventory, monitor stock levels, and reduce inventory losses.
4. We recommended that the Under Secretary for Health develop and implement local SDI patient data release processes to ensure compliance with Federal privacy statutes.
5. We recommended that the Under Secretary for Health provide appropriate clinical staff refresher training on VHA privacy and HIPAA requirements and their applicability to the release of SDI patient information.
6. We recommended that the Under Secretary for Health ensure that there are effective local policies and procedures to identify and follow up on all VA patients receiving post-operative care at non-VA facilities.
7. We recommended that the Under Secretary for Health submit the implant registry initiative to the Office of Information and Technology (OI&T) for development when funding becomes available.

### **Under Secretary for Health Comments**

The Under Secretary for Health agreed with the findings and recommendations of the report and provided acceptable implementation plans. (See Appendix C, pages 17–29, for the full text of the Under Secretary’s comments.) The Under Secretary also agreed with our estimated monetary benefits, with the caveat that the savings would be contingent upon the feasibility of obtaining national contracts and/or BPAs. He outlined plans to implement the National Item File (NIF), a management information and tracking system for all supplies, including SDI inventories, and efforts to standardize SDI nomenclature. He stated that VHA is reevaluating policies concerning the use of the PIP in managing prosthetics inventory. He also stated that the VHA Privacy Office has taken immediate action to address concerns raised about SDI patient data release practices. Lastly, the Under Secretary reported that VHA is completing the final revisions on two directives related to the recall of defective SDI, and it has submitted an implant registry initiative to OI&T for development to enhance VHA SDI recall processes. We incorporated technical comments provided by the Under Secretary into the report as appropriate. We will follow up on the implementation of the planned improvement actions.

*(original signed by:)*  
BELINDA J. FINN

Assistant Inspector General for Auditing

## Introduction

### Purpose

The purpose of the audit was to assess the effectiveness of VHA's acquisition and management of selected SDI. The objectives of the audit were to determine whether VHA facilities: (1) obtained the best prices for SDI not purchased under national contracts, (2) had adequate SDI inventory control procedures, (3) provided SDI manufacturers only the minimum amount of sensitive patient data needed for recalls, and (4) had effective policies and procedures to follow up on recalled SDI.

### Background

Under the Servicemen's Readjustment Act of 1944 (commonly known as the GI Bill of Rights of 1944), VA was charged with providing healthcare and rehabilitative services to veterans. On June 19, 1948, the 80<sup>th</sup> Congress passed Public Law 729 authorizing appropriations for VA to conduct research in prosthetics and sensory aids. VHA's PSAS provides a full range of prosthetics and sensory aids services to veterans, including durable medical equipment, artificial limbs, sensory aids, and SDI such as pacemakers and coronary stents. SDI are medical devices that are implanted in the body to replace and act as missing or defective biological structures. To monitor the procurement and utilization of orthotic, prosthetic, and sensory devices for VA patients, PSAS maintains information such as implant type, device cost, quantity purchased, and manufacturer in the NPPD.

During FY 2006, PSAS spent \$340 million (31 percent) of its \$1.1 billion in funding on SDI. In FY 2007, PSAS projects SDI spending will exceed \$562 million (46 percent) of its \$1.23 billion budget. In accordance with the purchasing hierarchy established by the Secretary's Procurement Reform Task Force in May 2002, VA purchases the majority of its SDI under national contracts or BPAs to leverage its buying power. However, VHA facilities purchase selected SDI—aortic valves, coronary stents, and thoracic grafts—through local contracts and the open market. For the 12-month period, July 2005 through June 2006, the NPPD reported that VHA facilities purchased 28,830 aortic valves, coronary stents, and thoracic grafts at a cost of over \$71.3 million.

### Scope and Methodology

To address our audit objectives, we identified applicable Federal regulations and VHA policies and procedures related to the acquisition and management of SDI. We also interviewed responsible VA, VHA, and PSAS program officials about SDI acquisition processes, inventory controls, the release of sensitive patient data, and implant recall policies and procedures. Our audit examined available NPPD data for the period July 2005 to June 2006; SDI recalls issued during calendar years 2005 and 2006; and SDI policies, procedures, and management controls in place during our onsite visits.



To determine if VHA facilities obtained the best prices for the selected SDI purchased through local contracts and the open market, we conducted a price survey of the 87 VHA facilities—medical centers, healthcare systems, and Veterans Integrated Service Networks (VISNs)—that reported purchases of aortic valves, coronary stents, and thoracic grafts in the NPPD during our review period. To conduct this price survey, we contacted each of the 87 VHA facilities to verify the selected SDI product lines they had purchased during our review period and the prices they had paid for each product line. (For the purposes of this report, a “product line” refers to a specific device offered by a manufacturer.) Using information from our price survey and the NPPD data for the 28,830 purchased SDI during our review period, we identified the lowest price a VHA facility had paid for each of the product lines included in the NPPD data. We considered the lowest or best prices identified for each product line to be reasonable estimates of what the prices would be if VHA negotiated national SDI contracts and BPAs. Consequently, we benchmarked the prices of the 28,830 SDI reported in NPPD against the best prices identified by our price survey to determine whether national contracts and BPAs might be more cost effective than local contracts and open market purchases. (See Appendix A on page 15 for a detailed description of our price survey and cost estimate methodology.)

From January through March 2007, we conducted onsite work at the Ralph H. Johnson VA Medical Center (VAMC) in Charleston, SC; the James A. Haley VAMC in Tampa, FL; the Palo Alto Health Care System (HCS) in Palo Alto, CA; and the Eastern Colorado HCS in Denver, CO. We also conducted a telephone survey of four additional VHA facilities and collected documents from these sites to assess controls over sensitive data of SDI patients and to evaluate the reliability of NPPD data and SDI price survey data we collected earlier.

To ensure that the NPPD data collected during our survey was sufficiently reliable for the purposes of our audit, we randomly selected transactions from the four sites we visited and four additional randomly selected sites using the Department of Health and Human Services (HHS) OIG’s RAT-STATS computer software. (RAT-STATS is a package of statistical software tools designed to assist a user in selecting random samples and evaluating audit results. The HHS OIG has used it since the early 1970s.) Table 1 lists the eight sites and the number of NPPD purchases we randomly selected at each VHA facility to verify the accuracy of the price data collected during our price survey.

**Table 1. Sample by Location and Surgical Implant**

Location		Surgical Implant		
		Coronary Stents	Aortic Valves	Thoracic Grafts
Atlanta VAMC	Purchases	156	20	127
	Sample Size	30	20	30
Eastern Colorado HCS	Purchases	243	17	4
	Sample Size	30	17	4
James A. Haley VAMC	Purchases	343	1	29
	Sample Size	30	1	29
Jesse Brown VAMC	Purchases	205	0	32
	Sample Size	30	0	30
Montana HCS	Purchase	166	0	1
	Sample Size	30	0	1
Palo Alto HCS	Purchases	215	21	11
	Sample Size	30	21	11
Ralph H. Johnson VAMC	Purchases	185	31	19
	Sample Size	30	30	19
Washington, DC VAMC	Purchases	148	27	14
	Sample Size	30	27	14
<b>Totals</b>	Purchases	1,661	117	237
	Sample Size	240	116	138

For each of the eight VHA facilities, we reviewed selected transaction data including purchase orders, invoices, and other supporting documents. We also collected and reviewed additional documents, such as contracts, memorandums, and correspondence to ensure the accuracy of our SDI price data. Our data reliability tests conducted on site and during our telephone survey disclosed that the computer-generated NPPD data and our price survey data were sufficiently reliable to address the objectives of this audit. To evaluate controls over SDI patient data security and recalls, we expanded our reviews in these areas to include implantable cardioverter defibrillators (ICDs) and pacemakers.

Our assessment of internal controls focused only on those controls related to our audit objectives. We reported lapses in patient data security identified during this audit, which did not directly address the audit's national scope and objectives, to VHA officials in a separate management advisory letter dated September 6, 2007. We conducted the audit in accordance with generally accepted government auditing standards.

## Results and Conclusions

### Issue 1: VHA Could Reduce the Prices Paid for Selected SDI

#### Findings

VHA could obtain lower prices for aortic valves, coronary stents, and thoracic grafts if it used national contracts and BPAs to procure these SDI. Although national contracts are the preferred method of procurement under VA's purchasing hierarchy, PSAS and the NAC had not made it a priority to pursue national contracts or BPAs for these selected SDI. As a result, VHA facilities procure these SDI through local contracts and the open market. Our review of NPPD data and our price survey of all 87 VHA facilities that purchased the selected SDI during our review period identified significant price differences among VHA facilities for the same implants. Some VHA facilities obtained significantly lower prices for the same implants than other VHA facilities. Negotiation of national contracts and BPAs for these selected SDI would reduce the variability in the prices VHA facilities pay for them. More importantly, it would allow VHA to leverage its buying power and obtain better prices nationwide. If VHA established national contracts and BPAs for these SDI and negotiated prices that approximated the lowest prices identified by our price survey, VHA could reduce its SDI costs by as much as \$21.7 million over the next 5 years.

**Local Procurement of the Selected SDI Created Significant Price Variances.** During the 12-month review period, the 87 VHA facilities purchased 28,830 aortic valves, coronary stents, and thoracic grafts at a cost of about \$71.3 million. Our price survey identified significant variances in prices VHA facilities paid during this period for 171 product lines. For example, within 3 months of each other, one VHA facility paid \$7,065 while another paid \$3,850 for the same aortic valve, a \$3,215 price variance. Table 2 presents summary price variance data for each of the reviewed SDI types.

**Table 2. Price Variances for SDI Product Lines**

<b>Surgical Implant</b>	<b>Number of Product Lines</b>	<b>Average</b>	<b>Low</b>	<b>Median</b>	<b>High</b>
Aortic Valves	28	\$ 1,726	\$ 33	\$ 1,840	\$ 3,250
Coronary Stents	45	\$ 655	\$ 57	\$ 550	\$ 1,810
Thoracic Grafts	98	\$ 198	\$ 3	\$ 96	\$ 1,478

At the local level, factors such as the experience levels and negotiation skills of the local contracting officers, the volume of the VHA facilities' SDI purchases, relationships between the SDI manufacturers and VHA facilities, as well as other variables influenced prices. At one VHA facility, we found that a VISN contracting officer's mistake in

recording a stent's price as \$2,890, instead of the negotiated price of \$2,600, on a contract's price schedule, increased the cost of each stent by \$290. Over the life of the contract, this error will increase the VHA facility's cost for this stent by more than \$197,261. However, the VHA facility cannot recoup the funds because the legally binding contract contains the higher price and includes terms and conditions that make it unfeasible for the VHA facility to terminate and renegotiate the contract.

At the time of our audit, the NAC had not negotiated national contracts and BPAs for these SDI because they believed the coronary stent market lacked the competition needed to effectively negotiate national contracts and that aortic valves and thoracic grafts were not a high priority compared to other high-volume items procured by VA. PSAS officials who monitor SDI procurements also did not identify the price variances and possible benefits of using national contracts and BPAs because VHA facilities did not use standardized naming conventions when entering product line information into NPPD. For example, different VHA facilities listed the same coronary stent product line in NPPD under multiple names such as "stent, coronary (SI523)," "stent 2.25MM X 12MM M-L Mini Vision RX," and "stent 4.0MM X 12 MM Cobalt Chromium RX." Consequently, PSAS officials could review general SDI information in the NPPD, such as type, quantity, price, and total purchases by VHA facility, but they could not compare information from different VHA facilities by product line.

**VHA Should Establish National Contracts and BPAs for Selected SDI.** VHA could reduce its annual costs for selected SDI by about \$4.34 million annually or \$21.7 million over 5 years. To estimate the cost differences between using national contracts and BPAs and local contracts and the open market to purchase the selected SDI, we first recalculated the costs of the 28,830 SDI purchased during our review period using the lowest product line prices identified during our price survey. Then we compared these estimated prices with the purchase prices reported in the NPPD during our review period. Table 3 compares the reported costs of the selected SDI purchased during the 12-month period with the estimated costs if the same SDI had been purchased under national contracts and BPAs. (See Appendix A on page 15 for a detailed discussion of our price survey and cost estimate methodology.)

**Table 3. Annual Estimated Cost Benefits from Negotiating National Contracts**

<b>Surgical Implant</b>	<b>Number of Purchased Implants</b>	<b>Costs of Locally Purchased Implants</b>	<b>Estimated Costs Under National Contracts</b>	<b>Estimated Cost Reduction</b>
Aortic Valves	1,383	\$8,014,889	\$7,166,175	\$848,714
Coronary Stents	21,463	53,359,006	50,033,135	3,325,871
Thoracic Grafts	5,984	9,944,749	9,776,030	168,719
<b>Totals</b>	<b>28,830</b>	<b>\$71,318,644</b>	<b>\$66,975,340</b>	<b>\$4,343,304</b>

We believe that the significant price variances identified by our audit demonstrate that VHA could reduce its costs if it established national contracts and BPAs for these

selected SDI. In addition, the arrival of another SDI manufacturer, Medtronic, to the coronary stent market later in calendar year 2007 should alleviate the NAC's concerns regarding the lack of competition in the coronary stent market. It could also stimulate enough market competition to decrease the negotiated prices of any national VHA stent contracts and BPAs to below those prices identified by our price survey.

Finally, besides the benefits of lowering SDI prices, national contracts could also reduce VHA's SDI expenses by promoting the consistent use of consignment agreements. Consignment agreements reduce VHA facilities' expenses by shifting the carrying costs of SDI inventory and inventory losses to the manufacturer. In a consignment agreement, vendors maintain a stock of supply items at the VHA facilities and charge the VHA facilities only when the items are used. VHA facilities can return unused or expired items to the vendors free of charge. None of the four VHA facilities we visited consistently used consignment agreements to procure SDI.

## **Conclusion**

VHA should establish national contracts and BPAs for aortic valves, coronary stents, and thoracic grafts to achieve lower SDI prices and reduce SDI expenses. Furthermore, PSAS could strengthen its oversight of VHA's procurement and utilization of SDI by standardizing NPPD to allow VISN-wide and national data analysis.

## **Recommendations**

1. We recommended that the Under Secretary for Health, within a year, evaluates VHA's aortic valve, coronary stent, and thoracic graft purchases; studies the feasibility of establishing national contracts and BPAs; and where indicated, initiates national contracts and BPAs.

The Under Secretary for Health agreed with our recommendation and stated that VHA fully endorses the establishment of national contracts and BPAs whenever possible for all high-use items, including surgical device implants. A Prosthetics Integrated Product Team has been actively pursuing opportunities to establish a national contract for coronary stents for almost 2 years. However, the few existing manufacturers of the coronary stents did not have an incentive to participate in requests for bids due to limited competition. Prosthetics and Clinical Logistics Office (PCLO) will renew efforts to pursue a national contract for the purchase of coronary stents now that other manufacturers may have recently entered the stent market. At the same time, the PCLO will establish a work group to assess the feasibility of establishing national contracts and/or BPAs for aortic valves and thoracic grafts. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.

2. We recommended that the Under Secretary for Health establish management controls to standardize NPPD data used to monitor SDI procurement and utilization.

The Under Secretary for Health agreed with the recommendation and stated that PCLO is developing a management information and tracking system, NIF, to identify all supply items, including SDI, by distributor and manufacturer part numbers. NIF will provide VHA standardized naming conventions and device-specific information needed to compare like items and perform in-depth analyses of national procurement trends. The Under Secretary also reported that PCLO will continue its efforts to standardize the nomenclature of selected surgical device implants identified in this report and to monitor the procurement and utilization of these devices via NPPD. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.

## Issue 2: Inventory Controls Would Improve Accountability

### Findings

VHA needs to ensure that its facilities have inventory controls to effectively manage and account for SDI. Although VHA policy requires VHA facilities to maintain perpetual inventory records for SDI in PIP, staff at three of the four VHA facilities we visited did not use PIP or any type of inventory control system to monitor and account for SDI. As a result, PSAS staff lacked reliable information regarding SDI stock stored in various locations at the VHA facilities, could not effectively manage purchased stock to prevent implants from expiring, and had no records regarding the disposition of expired SDI. During our 4 site visits, we inventoried 147 VHA-purchased aortic valves, coronary stents, and thoracic grafts valued at \$290,836. We found that 18 valves and grafts valued at \$34,381 (12 percent) had expired or would expire unused within the next 6 months after our site visits.

**VHA Facilities Needed To Establish Inventory Management Controls.** VHA required its facilities to use PIP to manage prosthetic inventory items, in response to the OIG's *Audit of Management of Prosthetics Supply Inventories at VA Medical Centers and the Denver Distribution Center*, (Report No. 99-00188-13, November 15, 1999). Nevertheless, three of the VHA facilities did not have any inventory system in place, and one used a locally developed inventory system, instead of PIP, to manage SDI. PSAS staff at the four VHA facilities chose not to use PIP for the selected SDI because they believed inclusion of the items in PIP would adversely affect their performance relative to VHA's 30-day inventory supply standard. They stated that they did not use PIP because surgical implants normally have a shelf life of 5 years, but items recorded in PIP were subject to the 30-day on-hand stock limit. The local PSAS staff were not aware that PIP allowed users to exclude a percentage of inventory items from the 30-day supply limit and that they could request an increase in the number of exclusions, if necessary, from PSAS. The VHA facilities' PSAS and Supply, Processing, and Distribution staff also expressed confusion about who was responsible for inventorying SDI.

Our inventories of SDI stock identified expired implants and implants that would expire within 6 months of our visit based on the VHA facilities' historical SDI usage rates. Of the 147 aortic valves, coronary stents, and thoracic grafts on hand that cost \$290,836, 18 items costing \$34,381 (12 percent) had expired or would expire within the next 6 months. Table 4 shows the expired SDI identified during our inventories and the related cost savings if staff used physical inventories and PIP to reduce expired stock.

**Table 4. Cost Savings from Implementing Inventory Controls and Reducing Expired SDI**

<b>Surgical Implant</b>	<b>Expired Implants</b>	<b>Cost of Expired Surgical Implants</b>	<b>Implants Expiring Within 6 Months</b>	<b>Cost of Expiring Surgical Implants</b>	<b>Total Cost</b>
Aortic Valves	0	0	4	\$24,400	\$24,400
Coronary Stents	0	0	0	0	0
Thoracic Grafts	5	3,249	9	6,732	9,981
<b>Totals</b>	<b>5</b>	<b>\$3,249</b>	<b>13</b>	<b>\$31,132</b>	<b>\$34,381</b>

The use of physical inventories and PIP would provide VHA facility staff the information they need to better manage SDI and reduce expired stock. Staff would be less prone to overstocking the selected SDI if they had accurate inventory information. Even if VHA facilities' must keep certain SDI in stock in order to provide emergent care, accurate inventory information would give them the opportunity to arrange credits and exchanges with manufacturers or to make SDI available to other VHA facilities before devices expire.

## Conclusion

If VHA established effective inventory controls to properly account for SDI, it could manage SDI inventory to minimize the amount of stock kept on hand and the risks of having missing, damaged, or expired SDI.

## Recommendation

3. We recommended that the Under Secretary for Health conduct physical inventories of SDI and use PIP to track inventory, monitor stock levels, and reduce inventory losses.

The Under Secretary for Health agreed with the recommendation and stated that PCLO is in the process of reevaluating and revising "VHA Directive 2001-005, National Prosthetic and Sensory Aids Service SHG Inventory Package," to facilitate compliance with inventory management mandates. The directive will include quality assurance and performance monitoring requirements for inventory management and a new requirement for facilities to conduct wall-to-wall inventories of all devices, including SDI. Furthermore, PCLO will develop an annual certification process to ensure that facilities comply with the new physical inventory requirements. The Under Secretary also reported that PCLO program managers will assess SDI inventory management practices during all upcoming medical facility site visits, with special emphasis on the facilities' use of PIP. Based on the site visit findings and the trending of compliance results, VHA will take necessary corrective actions. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.



## Issue 3: Patient Data Needs Safeguarding

### Findings

VHA needs to ensure that facility staff provide only the minimum necessary private medical information and sensitive personal data to implant manufacturers. VHA's Privacy Program requires privacy officers to ensure compliance with privacy statutes. Also, VHA's Privacy Program and HIPAA require VHA staff to limit the disclosure of patient information to the minimum amount necessary to fulfill legitimate requests. However, seven (88 percent) of the eight VHA facilities we reviewed had no procedures in place to identify specific SDI manufacturers' information requirements and to ensure the release of only the minimum amount of relevant patient information. As a result, clinical staff at the seven VHA facilities often provided SDI manufacturers patients' medical information and personal data that exceeded FDA requirements, placing veterans at risk for identity theft or other misuse of information for commercial advantage, personal gain, or malicious harm.

**VHA Facilities Did Not Limit Patient Sensitive Information Provided to SDI Manufacturers.** Clinical staff at the VHA facilities were aware of VHA privacy policies and related HIPAA requirements that require them to limit the disclosure of sensitive patient information to the minimum amount needed to satisfy requests. Yet staff at seven of the eight VHA facilities routinely provided sensitive patient data, such as patients' full names, social security numbers (SSNs), addresses, and dates of birth, to manufacturers verbally during procedures or through use of patient inquiry sheets. These disclosures occurred even though the SDI manufacturers had not requested all of this information and did not need the information to meet FDA recall requirements.

For example, two manufacturers of pacemakers and ICDs did not require patients' SSNs, but staff at the seven VHA facilities routinely provided SSNs to all SDI manufacturers. In addition, some manufacturer representatives received patient inquiry sheets to copy required patient information also received additional information shown on the sheets, such as the patients' service-connected disability ratings, religion, race, eligibility for VA benefits, employability ratings, and service-connected disabilities. Based on the patient information disclosure practices described above and the number of SDI implanted during our review period, we believe that as many as 156 patients at the 7 VHA facilities had more than the minimum amount of necessary medical information and personal data released to SDI manufacturers.

Local VHA Privacy Officers responsible for providing guidance on privacy related matters and for reviewing programs that collect, maintain, and store individually identifiable information had not developed or reviewed processes used to release SDI patient information to manufacturers. Also, clinical staff familiar with VHA privacy and HIPAA requirements did not properly apply this knowledge to ensure the release of only

the minimum amount of relevant patient data to manufacturers' representatives. These problems at seven of the eight reviewed VHA facilities indicate that other facilities could also be providing more than the minimum amount of needed medical information and sensitive patient information to SDI manufacturers.

## **Conclusion**

VHA did not ensure that clinical staff limited sensitive patient information provided to SDI manufacturers to information needed to comply with FDA recall requirements. Unnecessary disclosures of sensitive SDI patient information occurred because VHA facilities did not effectively implement VHA Privacy Program requirements governing the disclosure of information.

## **Recommendations**

4. We recommended that the Under Secretary for Health develop and implement local SDI patient data release processes to ensure compliance with Federal privacy statutes.

The Under Secretary for Health agreed with the recommendation and stated that on September 17, 2007, the VHA Privacy Office issued a Privacy Fact Sheet and Release of Information to Device Vendors Form (See Appendix C, Attachment 1, pages 27-29) to all facilities outlining the process for releasing SDI patient health information. The fact sheet emphasizes that staff must only release the minimum amount of personal identification information that vendors need to observe or assist in implantable device surgeries or to track their products. Facility Privacy Officers are responsible for ensuring that the fact sheet is widely distributed and implemented in their facilities and for revising local privacy policies to reflect language from VHA's newly revised Privacy Policy and Procedure template that restricts the release of SDI patient data. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.

5. We recommended that the Under Secretary for Health provide appropriate clinical staff refresher training on VHA privacy and HIPAA requirements and their applicability to the release of SDI patient information.

The Under Secretary for Health agreed with the recommendation and stated that the VHA Privacy Office has developed training material on the proper release of SDI patient information and that facility Privacy Officers will utilize the material during planned clinical staff refresher training. The Privacy Officers will train clinical staff within 90 days of receipt of the training material. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.

## Issue 4: Recall Procedures Need Improvement

### Findings

VHA needed to ensure that all VHA facilities implemented required recall procedures to prevent lapses in SDI patient care. The FDA issues a Class I recall when there is a reasonable chance that a device will cause serious health problems or death and a Class II recall when a device could possibly cause temporary or reversible health problems or there is a remote chance that the device will cause serious health problems. As a result, VHA policy requires VHA facilities to have procedures to address, review, and take action on defective medical device and medical product recalls. These requirements include maintenance of a system of records to document resolution of the recalls and notification of any additional parties needed to assist in implementation of the recalls. One (25 percent) of the four VHA facilities reviewed did not have an effective system in place to identify and track cardiology patients who were subject to SDI recalls. The VHA facility also lacked adequate documentation to show that it had taken action to resolve recalls. These lapses in the VHA facility's recall procedures occurred because staff believed that the recalls were the responsibility of the affiliated university providing the patients' post-operative care. Subsequently, it could not document that cardiology patients affected by SDI recalls had received follow-up care, and we confirmed that two patients had not received timely follow-up care.

**VHA Facility Did Not Establish Effective Recall Procedures.** At the 1 VHA facility that lacked adequate recall procedures for cardiology patients, we determined that 44 patients received timely, appropriate follow-up care, but 2 patients had not promptly received needed care after the recall of their ICDs.

- On June 17, 2005, a Class I recall for a Guidant® ICD indicated that a short circuit in the device could place patients' health and safety at risk. Accordingly, VHA issued guidance on July 7, 2005, stating that VA clinicians should identify affected VA patients within 2 weeks and provide follow-up care within 45 days. The VHA facility's staff identified a patient affected by this recall, but they did not ensure the patient received timely and appropriate follow-up care in accordance with the VHA guidance. As a result, the patient did not receive follow-up care until he came in for a routine cardiology appointment on October 27, 2006, 477 days after VHA issued the recall guidance.
- On February 11, 2005, a Class II recall for a Medtronic® ICD indicated that a short in the device's battery could place patients' health and safety at risk. VHA issued guidance on February 16, 2005, stating that VA clinicians should identify affected VA patients within 2 weeks and provide follow up within 90 days. However, neither the VHA facility nor the affiliated university identified the patient to provide prompt and appropriate follow-up care in accordance with the VHA guidance. As a result, the

patient did not receive follow-up care until his ICD “fired,” causing him to seek care on December 8, 2006, 660 days after VHA issued the recall guidance. When an ICD detects an abnormal heartbeat, it “fires” or gives the patient’s heart an electrical shock to return the heart to its normal rhythm. Although it is not required, many patients seek medical attention after their ICDs “fire.”

The National Program Director for Cardiology and the Director of the VA Western Pacemaker Program, who reviewed these cases at our request, concluded that the delayed follow-up care did not harm the two patients. However, we concluded that the VHA facility’s inadequate recall procedures and follow-up processes placed patients at unnecessary risk. According to the Director of the National Center for Patient Safety (NCPS), VHA has had problems recalling a variety of SDI because it has not established effective tracking systems at local and national levels. In response to this concern, VHA has proposed the establishment of an implant registry that will allow VHA facilities to easily identify and track patients affected by recalls. The VHA Informatics and Data Management Committee reviewed this initiative in July 2007 and assigned it “priority status” for development. Subsequently, VHA is currently waiting for the receipt of its FY 2008 funding allocations to determine if it has sufficient funding for all of the “priority status” development initiatives.

## **Conclusion**

VHA needs to ensure that VHA facilities have implemented recall processes and procedures that allow them to promptly identify and follow up on VA patients affected by recalled SDI. Furthermore, the development of an implant registry would improve VHA’s facility and national SDI recall processes by making it easier for staff to identify and track patients affected by recalls.

## **Recommendations**

6. We recommended that the Under Secretary for Health ensure that there are effective local policies and procedures to identify and follow up on all VA patients receiving post-operative care at non-VA facilities.

The Under Secretary for Health agreed with the recommendation and stated that the NCPS, through its Product Recall Office, will be responsible for establishing and coordinating national policy for the recall of defective medical devices and medical products. In addition, VHA will revise two directives to address the responsibilities of medical facility leadership in establishing and implementing local surgical implant recall policies and procedures. These revised directives will make it clear that all affected patients, including those patients receiving post-operative care at non-VA facilities, must be identified and personally contacted in the event of a recall. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.

7. We recommended that the Under Secretary for Health submit the implant registry initiative to the OI&T for development when funding becomes available.

The Under Secretary for Health agreed with the recommendation and stated that the Medical-Surgical Strategic Health Group in the Office of Patient Care Services has submitted the implant registry initiative to the OI&T. Pending funding availability, OI&T will develop the implant registry as part of the Prosthetics Enhancement project. We find the improvement plans acceptable, and we will follow up on the planned actions until they are completed.

## **Price Survey and Cost Estimate Methodology**

### **Survey Methodology**

To determine whether VA purchased coronary stents, aortic valves, and thoracic grafts at the lowest available price, we reviewed pricing data contained in the NPPD. We also conducted a price survey of the 87 VHA facilities that had purchased at least 1 of the 3 selected types of implants during our review period. During the price survey, we contacted each of the 87 VHA facilities to verify the accuracy of NPPD data, generate SDI price lists for each VHA facility, and identify the lowest price paid within VHA for the 171 product lines included in our population.

### **Population**

The population consisted of 28,830 aortic valves, coronary stents, and thoracic grafts purchased by VA from July 1, 2005, to June 30, 2006, at a cost of \$71,318,644.

### **Estimate Methodology**

We used data obtained from the 87 VHA facilities during our price survey to generate price lists for each of the 171 different SDI product lines and 28,830 SDI items in our population. Using these price lists, we identified the lowest or “best” price VHA had paid for each product line. We considered the “best” product line prices to be reasonable “target” prices for the negotiation and establishment of national contracts and BPAs. By adding the costs of the 28,830 SDI using the “best prices” identified for each product line, we estimated what the annual cost would be if VHA had negotiated national contracts and BPAs for these selected SDI.

To determine whether national contracts and BPAs might yield better SDI prices and lower SDI costs than local contract and open market purchases, we compared current SDI costs reported in NPPD with estimated SDI costs using the lowest or “best” prices identified during our price survey for the different product lines. Based on our calculations and cost comparisons for the 28,830 SDI, we estimated that VHA could reduce its annual costs for the 3 selected types of SDI by \$4.34 million if it established national contracts and BPAs for these SDI instead of using the open market and local contracts. Over a period of 5 years, this would equate to a cost reduction of about \$21.7 million.

## Monetary Benefits in Accordance with IG Act Amendments

<u>Recommendation</u>	<u>Explanation of Benefits</u>	<u>Better Use of Funds</u>	<u>Questioned Costs</u>
1	Better use of funds resulting from VHA leveraging its buying power over 5 years.	\$21,716,520	
1	Questioned costs because of contracting error.		\$197,261
3	Cost savings resulting from better use of PIP.	34,381	
	Total	\$21,750,901	\$197,261

## Under Secretary for Health Comments

**Department of  
Veterans Affairs**

### Memorandum

**Date:** September 25, 2007

**From:** Under Secretary for Health

**Subject:** Audit of the Acquisition and Management of Selected Surgical Device Implants

**To:** Assistant Inspector General for Auditing (52)

1. Thank you for the opportunity to respond to this draft report, which I have carefully reviewed. I concur in your findings and recommendations. Attached is Veterans Health Administration (VHA) plan of corrective actions in response to each recommendation. Based on findings from your price survey, I also agree with your estimate of monetary benefits if established national contracts and Blanket Purchase Agreements (BPA) were used in the purchase of SDIs rather than the open market and local contracts. Naturally, these savings estimates are contingent upon whether or not national contracts or BPAs are actually feasible when considering the surgical device implants highlighted in your audit.

2. In this regard, I want to emphasize a few points. VHA strongly encourages the use of national contracts and BPAs, and our Prosthetics and Clinical Logistics Office (PCLO) actively pursues such options in all areas of medical device and product purchasing, including SDIs. Your statement that “establishment of national contracts and BPAs for aortic valves, coronary stents, and thoracic grafts has not been a high priority” is somewhat misleading. In fact, a Prosthetics Integrated Service Team has attempted for almost 2 years to establish national contracts for the purchase of coronary stents, but to no avail, since the few manufacturers who produce stents were disinterested in bidding because they had no competitive incentive to do so. We have recently been advised that other manufacturers might be involved in



production of the stents, and the PCLO will again pursue possible national contract options. The PCLO also plans to establish a work group to explore the feasibility of establishing national contracts for aortic valves and thoracic grafts. Again, this possibility has been considered in the past, but the broad range of valve types, as well as the wide national variability in valve choice by surgeons, have made the possibility of national contracts seem unlikely. However, every effort will be made to establish the contracts. I am concerned about the wide variances in costs that you report for these items, and will direct the PCLO to offer possible purchasing alternatives if national contracts or BPAs are not feasible.

3. As our action plan details, many of the issues you identify involving standardization of data included in the National Prosthetics Patient Database (NPPD) and national monitoring of SDI procurement and utilization, will be successfully resolved with systematic implementation of the National Item File (NIF), a key management information and tracking system that will ultimately encompass tens of thousands of items, including SDI inventories. The NIF is being populated on an ongoing basis, and medical facilities are accessing the system throughout the building process. At the same time, PCLO will continue efforts to standardize the nomenclature of selected surgical device implants identified in your report and monitor procurement and utilization trends through the NPPD. Another key initiative, the implant registry, will further enhance overall surgical implant management. VHA has formally submitted a request for this initiative to the Office of Information and Technology.

4. VHA is also aware that facilities are frequently inconsistent in monitoring SDI inventories and in using the Prosthetics Inventory Package (PIP) in consolidating inventory records. The PCLO is currently re-evaluating related policies to identify and address existing administrative roadblocks. In this regard, VHA Directive 2001-005, dealing with the use of the package, is being revised to reflect expanded quality management monitoring requirements for inventory management. PCLO will also devise an annual certification process for facilities to ensure that the new inventory requirements are actually being accomplished at the local

level. In addition, PCLO program managers will routinely assess compliance during all scheduled medical facility site visits.

5. The VHA Privacy Office has also taken immediate action to address concerns you raise about SDI patient data release practices in some of our facilities. The attached Fact Sheet (Attachment A) was issued to all facility Privacy Officers on September 17, 2007, outlining processes for releasing personal patient data. The Privacy Policy and Procedure template that is used by facilities to draft local policies is also being revised to reflect restrictions on releasing SDI patient data. In the meantime, the Privacy Officers have been alerted that the template is being revised, and have been provided with the proposed language (Attachment B) that should be added to local privacy policies on this matter. In addition, the Privacy Office has developed relevant training material that will be used by facility Privacy Officers during clinical staff refresher training.

6. Lastly, I also support your recommendation that local policies and procedures be consistently developed and implemented to identify and follow-up on all VA patients with recalled SDI. The National Center for Patient Safety, the Office of Patient Care Services, the Office of Public Health and Environmental Hazards, the National Center for Ethics in Healthcare, and the Office of the Deputy Under Secretary for Health for Operations and Management, are currently completing final revisions to two related directives dealing with the recall of defective medical devices and medical products and with the disclosure of adverse events to patients. Both of these directives will update existing directives and specifically address national and local requirements for identifying and following up on VA patients with recalled surgical implants, including patients who might be receiving post-operative care in a non-VA facility.

7. In summary, I appreciate your assistance in highlighting improvement opportunities for our program managers. A copy of your report will be provided to all Network Directors for review and appropriate follow-up action. Identified concerns will also be widely communicated through established modes such as national conference calls, e-mail

distributions and web site postings. If additional information is required, please contact Margaret M. Seleski, Director, Management Review Service, at 565-7638.

*(original signed by:)*

Michael J. Kussman, MD, MS, MACP

Attachment

## **Under Secretary for Health Comments to Office of Inspector General's Report**

The following comments are submitted in response to the recommendations in the Office of Inspector General's report:

### **OIG Recommendations**

**Recommended Improvement Action 1.** We recommended that the Under Secretary for Health, within a year, evaluates VHA's aortic valve, coronary stent, and thoracic graft purchases; studies the feasibility of establishing national contracts and BPAs; and where indicated, initiates national contracts and BPAs.

Concur

**Target Completion Date:** December 2007

The Veterans Health Administration (VHA) fully endorses establishment of national contracts and Blanket Purchase Agreements (BPA) whenever possible for all high use items, including surgical device implants. A Prosthetics Integrated Product Team (IPT) has been actively pursuing opportunities to establish a national contract for coronary stents for almost 2 years. However, because of limited competitive incentive, the few existing manufacturers of the stents declined to participate in requests for bidding. The Office of Prosthetics and Clinical Logistics (PCLO) will renew efforts to pursue a national contract for the purchase of coronary stents. Opportunities for competitive bidding might be more successful since there is evidence that other manufacturers may have recently entered this competitive arena. At the same time, the PCLO will establish a work group to assess the feasibility of establishing national contracts or BPAs for aortic valves and thoracic grafts. While the high cost and volume of these devices certainly support the potential economic incentive for national contracts, other complexities make standardization difficult, including wide variation throughout the system in surgeon preference for specific devices. In addition, there are literally dozens of different

types of valves and grafts on the market, and the grafts are not limited to cardiac use. Nevertheless, the proposed work group will explore all aspects of contract feasibility and submit recommendations for future action.

**Recommended Improvement Action 2.** We recommended that the Under Secretary for Health establish management controls to standardize NPPD data used to monitor SDI procurement and utilization.

Concur

**Target Completion Date:** October 2008 and Ongoing

PCLO is in the midst of building a core management information and tracking system that is designed to ultimately capture tens of thousands of items, including SDI inventories. The National Item File (NIF) will identify all items by the distributor and manufacturer part numbers, thereby allowing VHA to have available the device specific information needed to compare like items and perform more in-depth analyses of national procurement trends. Significant resources, including a full-time technical staff, have been assigned to support development of this system, which is being populated on an ongoing basis; beginning with high cost, high quantity items and items included on national contracts. It is anticipated that the NIF will be completed early in FY 2009. Once the system is fully implemented, it is anticipated that issues dealing with lack of standardized naming conventions among facilities will be eliminated.

In the meantime, however, PCLO will continue efforts to standardize the nomenclature of selected surgical device implants identified in this report, and to monitor the procurement and utilization of these devices via the National Prosthetics Patient Database (NPPD). PCLO has already standardized NPPD data for other surgical device implants, such as pacemakers, implantable cardioverter-defibrillators (ICDs) and implant leads, and continues quarterly monitoring of these items.

**Recommended Improvement Action 3.** We recommended that the Under Secretary for Health conduct physical

inventories of SDI and use PIP to track inventory, monitor stock levels, and reduce inventory losses.

Concur

**Target Completion Date:** December 2007 and Ongoing

VHA is aware that facilities do not consistently apply adequate inventory controls in maintaining and accounting for SDI or follow VHA policy in utilizing the Prosthetics Inventory Package (PIP) to maintain inventory records for SDI. Recognizing the barriers that facilities frequently encounter in using PIP, the PCLO is in the process of re-evaluating existing policy with the goal of facilitating compliance with required inventory management mandates. For example, *VHA Directive 2001-005, National Prosthetic and Sensory Aids Service SHG Inventory Package*, is currently being reassessed and revised, with anticipated publication by the end of the First Quarter, FY 2008. Particular attention will be given to specifying quality assurance/performance monitoring requirements for inventory management, with a new requirement that facilities conduct wall-to-wall inventories of all devices, including SDIs. An annual certification process will also be developed by PCLO for feedback in ensuring that facilities are in compliance with the new physical inventory requirements.

In addition, PCLO program managers will conduct an assessment of surgical implant inventory management practices during all upcoming medical facility site visits that are conducted, with special emphasis on compliance by the facilities in utilizing the PIP. Based on the site visit findings, compliance trends will be evaluated, with corrective actions taken as indicated.

To further communicate expectations for facility tracking of all surgical device implants in the PIP, the PCLO will issue a memorandum to all prosthetic representatives, VISN Chief Logistics Officers and Chiefs of Staff re-emphasizing the importance of tracking all surgical implants in the PIP. A copy of this report will also be provided to all VISN Directors for review and follow-up.

**Recommended Improvement Action 4.** We recommended that the Under Secretary for Health develop and implement local SDI patient data release processes to ensure compliance with Federal privacy statutes.

Concur

**Target Completion Date:** October 2007 and Ongoing

On September 17, 2007, the VHA Privacy Office issued a Privacy Fact Sheet (Attachment 1) to all facilities outlining the process for releasing SDI patient health information, emphasizing that only minimum necessary standards are followed in releasing personal identification information to vendors assisting with implantable device surgery or observing surgery, or to vendors for the purpose of product tracking. VHA's Privacy Policy and Procedure template, which is used by facilities to draft local privacy policies, is also being revised to appropriately address restrictions on the release of SDI patient data. Prior to release of the revised template, the Privacy Office supplied the Privacy Officers with the proposed language that should be added to local privacy policies on this matter. This document, which is included in Attachment 1, was also distributed on September 17, 2007. The Privacy Officers are responsible for ensuring that the fact sheet is widely distributed and implemented in their facilities, especially in the surgical services, and that revisions to local privacy policies are made to reflect language included in the new template.

**Recommended Improvement Action 5.** We recommended that the Under Secretary for Health provide appropriate clinical staff refresher training on VHA privacy and HIPAA requirements and their applicability to the release of SDI patient information.

Concur

**Target Completion Date:** January 2008

The VHA Privacy Office has also developed training material on the proper release of SDI patient information that facility

Privacy Officers will be directed to utilize during planned clinical staff refresher training. As part of this effort, the Privacy Officers will be instructed to provide this training within 90 days of receipt of the training material.

**Recommended Improvement Action 6.** We recommended that the Under Secretary for Health ensure that there are effective local policies and procedures to identify and follow up on all VA patients receiving post-operative care at non-VA facilities.

Concur

**Target Completion Date:** December 2007

A revised VHA Directive, *Recall of Defective Medical Devices and Medical Products*, is currently undergoing final review prior to publication. When approved, this Directive will make the National Center for Patient Safety (NCPS), through its Product Recall Office, responsible for establishing and coordinating national policy for the recall of defective medical devices and medical products. Another related VHA Directive, *Disclosure of Adverse Events to Patients*, is also undergoing final review that will revise and update the current version. Both of these directives will address the responsibilities of medical facility leadership to establish and implement local policies and procedures to ensure that in the event of official recall of surgical implants (including SDIs), involved patients will be identified and personally contacted, including those patients who might be receiving post-operative care at non-VA facilities. Also, OIG's report will be distributed to all Network Directors, who will share the information with relevant staff, including the Network Recall Coordinators, for follow-up communication with the facilities.

**Recommended Improvement Action 7.** We recommended that the Under Secretary for Health submit the implant registry initiative to the Office of Information and Technology for development when funding becomes available.

Concur



**Target Completion Date:** Completed

The Medical-Surgical Strategic Health Group, Office of Patient Care Services has submitted the implant registry initiative request to the Office of Information and Technology. Pending funding availability and approval, the initiative will be developed as part of the Prosthetics Enhancement project.

## Under Secretary for Health Comments



*Health Data and Informatics*  
VHA Privacy Office

# Privacy Fact Sheet

September 2007

Volume 07, No. 4



### Disclosing the Minimum Amount of Protected Health Information (PHI) to Vendors Assisting with Implantable Devices or Observing Surgery

Often, when implantable devices such as stents or heart pacemaker devices are being placed into patients during a surgery, the vendor who supplies these devices is in attendance to assist with the implantation or the calibration of the implanted device. In these cases, these vendor representatives are considered to be health care providers assisting with the care of the patient and any disclosures to them are as health care providers. In addition, after the surgery, VHA often discloses information to the vendor in order for them to contact the patient in the event of a recall of the implanted device and will ask for specific information for their records in order to contact the patient, if needed. Though the minimum necessary standard in the HIPAA Privacy Rule does not apply to disclosures to or requests by a health care provider for treatment (Ref. 45 CFR §164.502(b)(2)(i)), VHA will still apply the minimum necessary standard when disclosing information to vendors. The disclosure to the vendor is made not only for treatment purposes but also for public health tracking required by the Federal Drug Administration (FDA) for implantable devices. Although there is sufficient legal authority to make the disclosure under the HIPAA Privacy Rule for these two purposes, it is vital that only the minimum necessary amount of information be disclosed to the vendor.

In some recent cases, VA Medical Center Operating Room staff has given more information to these vendors than was requested by the vendor which breaches the HIPAA Privacy Rule minimum necessary standard. **It is critical that only the requested amount of information is provided to these vendors and that VHA maintain an accounting of these disclosures in the Release of Information department.**

Vendors may also request to be allowed to observe the implantation of devices that their company sells in order to learn about these surgeries or learn how to assist in the future. In these cases where the vendor is not actually participating in the surgery, but is only observing, a signed, written authorization from the patient must be obtained before allowing disclosures to the vendor or allowing the vendor to view the surgery. This is because they will be allowed to hear information, see the patient being operated on and as a result, have information disclosed to them. See the December 2003 Privacy Fact Sheet, Vol. 04, No. 1 - Vendor Reps in Surgical Suites, available at <http://vaww.vhaco.va.gov/privacy/FactSheets.htm> for additional information. Since the vendor is not acting in the capacity of a health care provider and is only an observer for their own purposes and not for the purpose of assisting VHA in the surgery, the only authority to allow them to have access to the information disclosed during the surgery is by having the patient sign a HIPAA-compliant authorization. This must be accomplished in the following manner:

- The patient must be informed that the vendor wants to observe the surgery for the purpose of learning how the device is implanted;
- The patient must be willing to have the vendor in attendance; and
- The patient must complete VA Form 10-5345 prior to their surgery authorizing the disclosure of information to the vendor.

**Note: For information on photos taken during surgery or suggested readings on this topic -Surgical Setting Fact Sheet which can be found on the VHA Privacy Office web site at: <http://vaww.vhaco.va.gov/privacy/Communications/FactSheetVol04No1.doc>**

<p><b><i>Privacy Office at a glance...</i></b> VHA-specific privacy questions: VHA personnel should contact their Privacy Officer or VHA Privacy Office at 321-504-4574. <b>Website:</b> <a href="http://vaww.vhaco.va.gov/privacy">http://vaww.vhaco.va.gov/privacy</a></p>
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## Under Secretary for Health Comments

### Release of Information to Implantable Device Vendors

When implantable devices such as stents or heart pacemaker devices are being placed into patients during a surgery, the < INSERT Facility Name > will follow the minimum necessary standard as outlined in VHA Handbook 1605.2 when making disclosures to vendors assisting with the implantation or calibration of these devices. Though the minimum necessary standard in the HIPAA Privacy Rule does not apply to disclosures to or requests by a health care provider for treatment (Ref. 45 CFR §164.502(b)(2)(i)), VHA will still apply the minimum necessary standard when disclosing information to vendors. The disclosure to the vendor is made not only for treatment purposes but also for public health tracking required by the Federal Drug Administration (FDA) for implantable devices. Therefore, only the requested amount of information will be disclosed to the vendor when providing or releasing information for the purpose of tracking the device in the event of a recall.

Vendors may also request to be allowed to observe implantation of devices that their company sells in order to learn about these surgeries or learn how to assist in the future. In these cases where the vendor is not actually participating in the surgery, but is only observing, a signed, written authorization from the patient must be obtained before allowing disclosures to the vendor or allowing them to view the surgery. This must be accomplished in the following manner:

- The patient must be informed that the vendor wants to observe the surgery for the purpose of learning how the device is implanted;
- The patient must be willing to have the vendor in attendance; and
- The patient must complete VA Form 10-5345 prior to their surgery authorizing the disclosure of information to the vendor.

If the vendor requests to take a photograph of the implantation, the patient must also sign VA Form 10-3203 for authorization to take the photograph in addition to the VA Form 10-5345 for authorization to disclose information.

All disclosures made to implantable device vendors must be reported to the Release of Information Department for inclusion in the ROI Records Management Software so that an accounting of the disclosures is maintained.

## OIG Contact and Staff Acknowledgments

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OIG Contact	Janet Mah (310) 268-4335
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Acknowledgments	Randy Alley Corina Riba Andrew Hamilton John Powers Andrea Lui
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## Report Distribution

### **VA Distribution**

Office of the Secretary  
Veterans Health Administration  
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This report will be available in the near future on the OIG's Web site at <http://www.va.gov/oig/publications/reports-list.asp>. This report will remain on the OIG Web site for at least 2 fiscal years after it is issued.