U.S. Department of Health and Human Services
Office of Inspector General

Spinal Devices Supplied By Physician-Owned Distributors: Overview of Prevalence and Use

Daniel R. Levinson
Inspector General

October 2013 | OEI-01-11-00660

EXECUTIVE SUMMARY: SPINAL DEVICES SUPPLIED BY PHYSICIAN-OWNED DISTRIBUTORS: OVERVIEW OF PREVALENCE AND USE OEI-01-11-00660

WHY WE DID THIS STUDY

This report responds to a congressional request to determine the extent to which physician-owned distributorships (PODs) provide spinal devices to hospitals. PODs' physician-owners can include the surgeons who implant the PODs' devices; these owners have an opportunity to profit from using the devices their PODs sell. Critics of PODs claim that such ownership creates a conflict of interest that may affect physicians' clinical decisionmaking. PODs assert that their devices cost less than devices provided by other spinal device companies.

HOW WE DID THIS STUDY

We selected a sample of 1,000 claims billed to Medicare in fiscal year (FY) 2011 that included spinal fusion surgery. We asked each hospital associated with these claims to complete a questionnaire about its knowledge of physician ownership of spinal device suppliers. We also asked each hospital to complete a worksheet with details about the spinal devices used in each surgery in our sample.

WHAT WE FOUND

In FY 2011, PODs supplied devices used in nearly one in five spinal fusion surgeries billed to Medicare. Spinal surgeries that used POD devices used fewer devices but did not have lower per surgery device costs than surgeries that did not use POD devices. Among the hospitals in our sample, about a third reported buying spinal devices from PODs. When hospitals in our sample began buying from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall. Finally, in FY 2012, surgeons performed more spinal surgeries at hospitals in our sample that purchased from PODs than at those that did not purchase from PODs.

WHAT WE CONCLUDE

PODs are a substantial presence in the spinal device market. Our findings raise questions about PODs' claim that their devices cost less than those of other suppliers. Surgeons performed more spinal surgeries at hospitals that purchased from PODs, and those hospitals experienced increased rates of growth in the number of spinal surgeries performed in comparison to the rate for hospitals that did not purchase from PODs. Taken together, these factors may increase the cost of spinal surgery to Medicare over time. Finally, hospitals' policies varied in whether they required physicians to disclose ownership interests in PODs to either the hospital or their patients. Thus the ability of hospitals and patients to identify potential conflicts of interest among these providers is reduced.

TABLE OF CONTENTS

Objectives 1

Background 1

Methodology 5

Findings 8

In FY 2011, PODs supplied the devices used in nearly one in five spinal fusion surgeries billed to Medicare 8

Spinal fusion surgeries that used PODs devices used fewer devices but did not have lower device costs 8

About a third of hospitals in our sample purchased spinal devices from PODs 10

When hospitals in our sample began purchasing devices from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall 13

In FY 2012, hospitals in our sample that purchased from PODs performed more spinal surgeries than those that did not purchase from PODs 16

Conclusion 18

Appendixes 19

A: Detailed Methodology 19

B: Confidence Intervals 25

C: Distribution of Sampled Surgeries by State 26

Acknowledgments 27

OBJECTIVES

1. To determine the extent to which spinal fusion surgeries used spinal devices provided by physician-owned distributors (PODs).
2. To determine whether the cost and quantity of spinal devices used in spinal fusion surgeries differed when spinal devices were supplied by PODs.
3. To determine the extent to which hospitals associated with a sample of spinal fusion surgeries purchased spinal devices from PODs.
4. To determine whether the rates and complexities of spinal surgeries differed when hospitals associated with a sample of spinal fusion surgeries purchased spinal devices from PODs.

BACKGROUND

In fiscal year (FY) 2012, Medicare paid hospitals a total of $3.9 billion for 178,789 spinal surgeries. Medicare reimbursed hospitals an average of $21,613 for each of these surgeries. On average, Medicare reimbursed hospitals $10,289 for the least complicated spinal surgeries and $34,676 for the most complicated surgeries.

This report responds to a congressional request. The requestors expressed concerns about the growth of physician-owned distributorships and the potential adverse effect that these entities could have on Medicare beneficiaries and Federal health care programs. The requestors asked the Office of Inspector General (OIG) to examine a number of issues regarding PODs. In response, OIG stated that it would determine the extent to which PODs provide spinal devices to hospitals.

Overview of Physician-Owned Device Companies

Companies not owned by physicians most commonly supply spinal devices to hospitals through their staff or contracted sales representatives. These sales arrangements may also provide other services, such as operating-room technical support, inventory management, and coding assistance.

Some physicians, including surgeons who implant spinal devices, have ownership stakes in spinal device companies. For the remainder of this report, we will refer to such companies as PODs.

Physicians invest in a variety of POD arrangements. PODs vary in (1) whether their physician-investors practice in the hospitals to which they distribute devices, (2) whether they solely distribute devices or both manufacture and distribute their own devices, and (3) which services they

offer along with the purchase of their devices. Regardless of the business arrangement, PODs offer physician-investors the opportunity to profit from using the devices their PODs sell.

Controversy Over PODs

Benefits of PODs. PODs assert that they supply spinal devices at a lower cost than companies not owned by physicians. They claim to reduce costs to hospitals by lessening the need for sales representatives, procuring inventory from smaller manufacturers, and increasing competition in the market for devices.

Vulnerabilities of PODs. Critics of PODs claim that PODs create a conflict of interest that could affect physicians' clinical decisionmaking. Ownership may encourage surgeons to perform unnecessary and inappropriate spinal surgeries to drive sales for their companies. Critics claim that surgeons may also perform more spinal refusion surgeries, also known as revision surgeries. These surgeries sometimes involve removing previously implanted devices and replacing them with new devices. Critics claim that PODs may encourage surgeons to perform these surgeries.

PODs potentially raise legal concerns under the Anti-Kickback Statute. The statute makes it a criminal offense to knowingly and willfully offer remuneration to induce, or in return for, referrals of items of services reimbursable by a Federal health care program.[1] By its terms, the statute ascribes criminal liability to parties on both side of an impermissible "kickback" transaction.[2]

In 2013, OIG released a Special Fraud Alert on Physician Owned Entities. OIG stated that PODs are inherently suspect under the Anti-Kickback Statute and set forth a number of suspect characteristics about which it is concerned.[3] OIG is particularly concerned about PODs because surgical implants "typically are 'physician preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than the hospital where the procedure is performed."[4] The Fraud Alert echoes OIG guidance from 2006 that specifically addressed physician investments in medical device manufacturers and distributors. In that guidance, OIG acknowledged the "strong potential for improper inducements between and among the

[1] Section 1128B(b) of the Social Security Act.
[2] Ibid.
[3] OIG Special Fraud Alert, Physician Owned Entities (Mar. 2013). Accessed at http://oig.hhs.gov on May 13, 2013.
[4] Ibid.

physician investors, the entities, device vendors, and device purchasers" and stated that such arrangements should be "closely scrutinized under fraud and abuse laws."[5]

The Sunshine Act

Hospitals and patients may be unaware of physicians' investment in PODs. However, regulations that the Centers for Medicare & Medicaid Services (CMS) recently issued under the Physician Payments Sunshine Act will require PODs to become more transparent.[6] As of August 1, 2013, CMS requires manufacturers and group purchasing organizations to report all physician ownership and investment interests to CMS annually.[7] The regulations define group purchasing organizations as including most PODs, but CMS may determine, on a case-by-case basis, whether it considers a particular POD arrangement to be a group purchasing organization under the final rule.[8] CMS will make a database of compensated physicians publicly available.

Spinal Procedures and Devices Associated With Spinal Surgeries

Spinal surgery often involves implanting devices that immobilize or reduce pressure on the spine. Some of the indications for spinal surgery are disc degeneration, spinal stenosis, fractures, tumors, and vertebral instability.[9] Two common spinal procedures—spinal fusion and decompression—often involve implanting medical devices and biologics (such as bone grafts). Each spinal surgery may involve one or more spinal procedures.

Spinal Fusion Procedures. Spinal fusion is considered either simple or complex depending on the number of vertebrae fused. Simple spinal fusion joins two or three vertebrae to one another, often using both bone grafts and devices to immobilize the vertebrae. Complex spinal fusion involves fusing more than three vertebrae using similar devices and grafting techniques.[10]

Decompression Procedures. Decompression is performed to relieve pressure on the spinal cord and/or nerve roots. To do this, surgeons might remove bone spurs and part or all of a lamina, vertebra, or spinal disk.

---

[5] Ibid.

[6] The Physician Payments Sunshine Act was part of the Patient Protection and Affordable Care Act, P.L. 111-148 § 6002, Social Security Act, § 1128G.

[7] 42 CFR § 403.906.

[8] 42 CFR § 403.902; 78 Fed Reg 9458, 9493 (Feb. 8, 2013).

[9] OrthoInfo, *Spinal Fusion*. Accessed at http://orthoinfo.aaos.org/ on Oct. 20, 2013.

[10] We defined "complex spinal fusion" and "simple spinal fusion" according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure codes.

Surgeons might also use a device to expand the openings where nerves exit the spinal cord. Surgeons can perform a spinal fusion in conjunction with decompression, depending upon the extent of the decompression procedure and its impact on the stability of the spine.[11]

Spinal Devices. Spinal procedures may involve implanting a number of different spinal devices, including plates, screws, pedicle screws, rods, cap/set screws, and interbody cages. Plates and screws are used in conjunction with one another to properly align vertebrae. Surgeons stabilize the spine either by affixing the plate directly to the vertebral bone with screws or by inserting pedicle screws into adjacent vertebrae and connecting screws with rods. Cap/set screws are used to affix rods to pedicle screws. Interbody cages are implanted between vertebrae to host the bone graft used to fuse adjacent vertebrae. The interbody cage helps maintain height between vertebrae as the bone graft hardens.

Medicare Payment for Spinal Surgery Using Spinal Devices

Medicare covers only spinal implant surgery performed in the inpatient setting. It makes separate payments for surgeons' professional fees and for hospitals' facility charges. Medicare Part B pays surgeons under the Medicare Physician Fee Schedule. Medicare Part A pays the hospitals under the Inpatient Prospective Payment System (IPPS).

Under the IPPS, Medicare classifies each case into one of 747 medical severity diagnosis related groups (MS-DRG). These groups are based on the beneficiary's diagnoses and the procedures performed, as well as other factors reported by the hospital on the claim. Payment for the MS-DRG covers nearly all costs associated with the hospital stay, including any spinal devices implanted into the beneficiary.

[11] The Cleveland Clinic, *Spinal Decompression Surgery, Treatments and Procedures*. Accessed at http://my.clevelandclinic.org on Oct. 14, 2011.

METHODOLOGY

This study used Medicare claims and enrollment data, a review of the spinal devices implanted during a representative sample of spinal fusion surgeries billed to Medicare, and questionnaire responses from the hospitals that billed for Medicare for these surgeries. See Appendix A for a full discussion of our methodology.

Scope

This study is national in scope. For the purposes of this study, we defined "spinal surgery" as spinal decompression and spinal fusion. Our sample of claims included surgeries that involved a spinal fusion procedure and were billed to Medicare during FY 2011. We sampled such claims because surgeries involving spinal fusion were more likely to use implanted spinal devices than surgeries that involved only decompression. We did not make any judgment on the legality of hospitals' relationships with PODs or on the appropriateness of spinal surgeries performed by hospitals.

Sample Selection

We selected a simple random sample of 1,000 claims for spinal fusion surgery from Medicare's Standard Analytical File of 100-percent inpatient claims for FY 2011. After clearing the 615 hospitals associated with these claims with OIG's Office of Investigations, we removed 29 claims from 19 hospitals from our sample. Our data collection sample included 971 claims from 596 hospitals.

Data Collection

We administered a questionnaire to hospitals and asked them to complete an invoice worksheet using secure Web-based survey software. We made three attempts to obtain responses. Of the 596 hospitals that we asked to complete the questionnaire, 589 hospitals responded. These hospitals also provided invoice information for 963 of the 1,000 claims included in our sample.[12] Our overall response rate was 96 percent.

Hospital Questionnaire. We asked each hospital that billed for one or more spinal surgeries in our sample to answer a series of questions about the entities from which it purchases spinal devices. As part of those questions, we asked each hospital about its awareness of physician ownership among its suppliers of spinal devices. We defined "physician owners" as those with a partial or full ownership stake through private investment, excluding stock in a publicly traded company.

[12] Five of the hospitals in our sample refused to provide invoice information detailing spinal devices implanted during eight inpatient stays covered by Medicare. We will refer these hospitals to CMS.

Invoice Review. We asked each hospital to complete a worksheet for each of its spinal surgeries in our sample. The worksheet compiled detailed data about the spinal devices used for the surgery and the entities that supplied them to the hospital. We asked hospitals to substantiate the data they provided on the worksheets by sending us hard copies of supporting documents, such as invoices and purchase orders.

Data Analysis

We analyzed data from the invoice review and the hospital questionnaire responses to determine the extent to which spinal surgeries used spinal devices provided by PODs and whether the cost or quantity of spinal devices used in these surgeries differed for POD-provided devices.

To determine the extent to which hospitals associated with our sample of claims purchased spinal devices from PODs, we analyzed data from the questionnaire responses and the invoice review. We counted hospitals as purchasing from PODs if they self-identified as using PODs in the responses or invoice review or if we identified such purchasing by cross-referencing these two data sources.

We analyzed data from the questionnaire responses to explain why hospitals purchased spinal devices from PODs and determine the extent to which they had policies on physician disclosure of ownership in medical device companies.

To determine whether rates and complexities of spinal surgeries differed when hospitals purchased from PODs, we analyzed hospitals' Medicare claims to describe their spinal surgery caseloads both (1) before and after they began purchasing from PODs and (2) in FY 2012. We used three measures to describe the complexity of hospitals' caseloads: the percentage of spinal surgery caseload that was spinal fusion, the percentage that was complex spinal fusion, and the percentage that was refusion surgery.

Limitations

This study relies on Medicare claims and the hospital questionnaire responses, which were self-reported by hospitals. We did not independently verify these data. Certain findings are limited to the hospitals associated with our sample of claims and are not generalizable. We describe changes in utilization rates over time, but did not determine the cause of those changes. We relied on ICD-9-CM procedure codes reported by hospitals on Medicare claims to determine the type and complexity of spinal procedures. We also did not assess the clinical benefits or equivalency of POD devices and non-POD devices.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In FY 2011, PODs supplied the devices used in nearly one in five spinal fusion surgeries billed to Medicare

PODs supplied spinal devices for 19 percent of the spinal fusion surgeries billed to Medicare in FY 2011. Of the surgeries that used POD devices, about two-thirds used a mix of such devices and devices that were not from PODs. About one-third of these surgeries used only POD devices.

The distribution of surgeries that used POD devices varied geographically (see Appendix C). Surgeries from California and Texas composed one quarter of the surgeries in our sample that used POD devices, with 14 and 11 percent, respectively. Just over a quarter were performed in Missouri (6 percent), Florida (6 percent), Pennsylvania (5 percent) Alabama (5 percent), and Georgia (5 percent).

Spinal fusion surgeries that used POD devices used fewer devices but did not have lower device costs

Critics of PODs argue that because PODs link surgeons' compensation to the number of devices they implant, they have the potential to increase the number of devices used during spinal surgeries. However, proponents of PODs claim that PODs reduce the cost of spinal devices by lessening the need for sales representatives and increasing competition in the spinal device market. Medicare payment is tied to the MS-DRG classification of the hospital stay, so any difference in device costs would not immediately affect the amount Medicare or the beneficiary paid for a given stay. However, Medicare payment to hospitals could change over time as device costs are factored into hospitals' Medicare reimbursement through cost reporting.

Surgeries that used POD devices used about two fewer devices per surgery than surgeries that did not use POD devices

Overall, surgeries that used POD devices implanted an average of 12.3 spinal devices compared to an average of 14.2 spinal devices for surgeries that did not implant POD devices. The number of devices implanted during complex spinal fusion surgeries accounts for this difference. Complex spinal fusion surgeries that used POD devices implanted an average of 16.5 devices compared to an average of 23 devices for complex spinal fusion surgeries that did not implant POD

devices.[13]

Device costs for surgeries that used POD devices were not lower than those for all other surgeries

We did not find a statistically significant difference between the average total device cost for spinal surgeries that used POD devices and those that that did not use POD devices.[14]

Furthermore, none of the six types of spinal devices we examined was less costly per unit when provided by PODs, and one was more costly when provided by PODs (see Table 1). Using data from the invoice review, we determined and compared the prices that hospitals paid PODs and distributors not owned by physicians for rods, cap/set screws, pedicle screws, interbody fusion devices, spinal plates, and other screws. We found no statistical difference between the price hospitals paid PODs and distributors not owned by physicians for rods, cap/set screws, pedicle screws, other screws, and interbody fusion devices. However, we found that hospitals paid $845 more for spinal plates from PODs. This difference could eventually raise a hospital's Medicare reimbursement through increased device costs in its cost reporting.

Table 1: Average Cost of Spinal Devices by Device Type

Device Type	Cost of POD Devices	Cost of Non-POD Devices	Statistically Significant Difference
Spinal plates *	$2,475	$1,630	$845
Other screws †	$699	$620	-
Interbody fusion devices, non-bone †	$2,821	$2,998	-
Pedicle screws †	$942	$892	-
Rods †	$345	$360	-
Cap/set screws †	$142	$148	-

Source: OIG analysis of hospital questionnaire responses and invoice worksheet data, 2013.
* Denotes a statistically significant difference at the p<.05 level.
† Denotes no statistically significant difference at the p<.05 level.

[13] Complex spinal fusion surgeries make up over a fifth both of surgeries that use POD devices and surgeries that do not use POD devices (21 and 25 percent, respectively).
[14] The average total device cost for surgeries that used POD devices was $11,601 and the average total device cost for surgeries that did not use POD devices was $11,383. The difference between these two averages is not statistically significant at the .05 level.

About a third of hospitals in our sample purchased spinal devices from PODs

Thirty-four percent of hospitals in our sample (203 of 589 hospitals) purchased spinal devices from PODs. About three-fifths, or 119, of those hospitals self-identified on the questionnaire responses as having purchased from PODs. We identified the remaining two-fifths, or 84 hospitals, by cross-referencing PODs that hospitals identified in their responses with device suppliers that hospitals reported on their invoice worksheets (see Table 2).

Table 2: Types of Hospitals in Our Sample

Hospital Type	Number of Hospitals
Hospitals that purchased from PODs	203
Self-identified hospitals	*119*
Cross-referenced hospitals	*84*
Hospitals that did not purchase from PODs	386
All hospitals in our sample	**589**

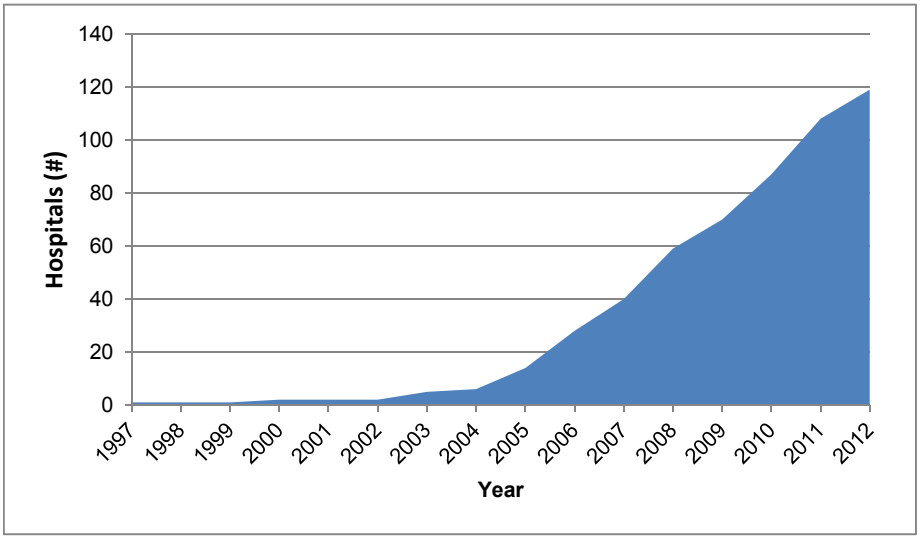
Source: OIG analysis of hospital questionnaire responses and invoice review, 2013.

The following analysis is limited to the 119 hospitals that reported in their questionnaire responses that they used PODs. We analyzed this subset of hospitals because our questionnaire collected additional details about hospitals' interactions with PODs only when hospitals self-identified as purchasing from PODs. We were unable to collect these details for the hospitals that we identified through our cross-reference as purchasing from PODs.

Most hospitals began purchasing spinal devices from PODs in the last 10 years

Hospitals reported purchasing from PODs as early as 1997. However, the majority (88 percent) of hospitals that purchased from PODs began doing so after 2005. Nearly half (41 percent) of hospitals that purchased from PODs began doing so recently, between 2010 and 2012 (see Chart 1 on the following page).

Chart 1: Hospitals in Our Sample That Purchased Spinal Devices From PODs, by Year



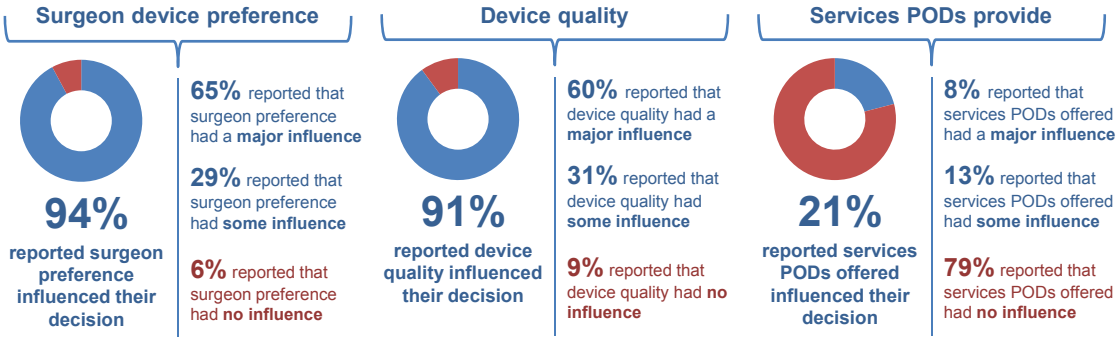
Source: OIG analysis of hospital questionnaire responses, 2013.

Hospitals identified surgeon preference as the strongest influence on their decisions to purchase spinal devices from PODs

Ninety-four percent of hospitals that purchased from PODs reported that surgeon preference influenced their decision to purchase from PODs. Surgeons often develop a preference for a company's devices after they gain familiarity and experience with that company's devices. Hospitals ranked surgeon preference over quality and effectiveness of devices as factors that influenced their decision to purchase spinal devices from PODs. About 90 percent of hospitals reported that quality and effectiveness also influenced their decision. Although about three quarters of hospitals that purchased devices from PODs reported that they received additional services from them, only about 20 percent of hospitals reported that those services influenced their decisions to purchase from PODs (see Figure 1 on the following page).[15]

[15] In addition to supplying devices, PODs and distributors not owned by physicians often provide services to hospitals, such as technical and administrative support. About three quarters of hospitals reported that they received technical support from PODs in the operating room. Thirty-one percent of hospitals received assistance from PODs to manage their inventory of spinal devices. Ten percent of hospitals received help from PODs with coding to bill for their devices. Non-physician owned companies offer similar services.

Figure 1: Factors That Influenced Hospitals' Decisions To Purchase From PODs



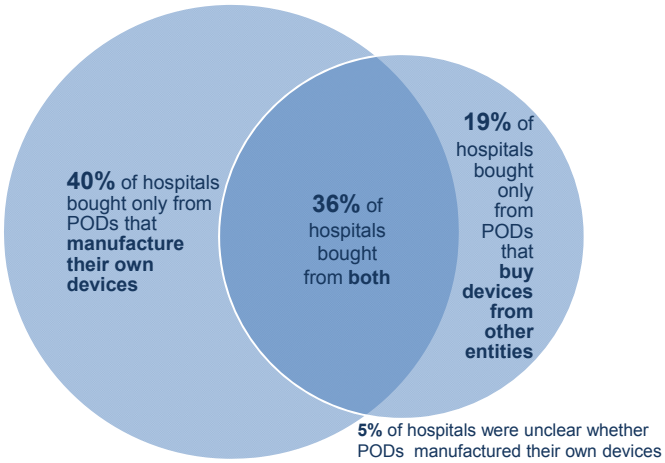
Source: OIG analysis of hospital questionnaire responses, 2013.

Many hospitals purchased spinal devices from PODs owned by physicians practicing in their hospitals

PODs are owned by physicians practicing inside or outside the hospitals they sell spinal devices to. About two-thirds of hospitals reported that they purchased from PODs owned by physicians practicing in their hospitals.

PODs also varied by whether they distributed devices that they manufactured or devices manufactured by others. Three-quarters of hospitals purchased spinal devices from PODs that manufactured their own devices (see Figure 2).

Figure 2: Hospitals' Use of PODs by PODs' Manufacturing Capabilities



Source: OIG analysis of hospital questionnaire responses, 2013.

Most hospitals did not purchase exclusively from PODs. Ninety-four percent of hospitals that purchased spinal devices from PODs also purchased devices from companies not owned by physicians.

Hospitals were not always aware of physician investment in spinal

device companies. About 40 percent of hospitals that purchased from PODs were uncertain whether one or more of their other suppliers were PODs.

Over half of hospitals had policies requiring physicians to disclose ownership stakes in device companies to the hospitals; far fewer required physicians to disclose to patients

Although Federal law does not require physicians to disclose ownership stakes in device companies to hospitals they practice in, 65 percent of hospitals had policies requiring them to do so. Disclosure policies can help hospitals and patients identify whether their physicians have potential conflicts of interest through investment in medical device companies.

Hospitals' disclosure policies varied. Some hospitals noted only requiring physicians to disclose ownership during the credentialing or hiring process. Furthermore, some hospitals noted that they required disclosure only from certain types of employees, such as managers and administrators.

Only 8 percent of hospitals that purchased from PODs reported that they required physicians to disclose to their patients whether they have ownership stake in the device companies they use.[16] Federal law does not require physicians to disclose such ownership to their patients.

When hospitals in our sample began purchasing devices from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall

The presence of PODs may encourage surgeons to perform more surgeries or more complex surgeries to increase device sales. To explore this issue, we compared rates of spinal surgeries performed at hospitals in the sixth month before they started purchasing from PODs and in the sixth month after they started purchasing from PODs. We compared changes in these rates between two groups of hospitals: all hospitals that billed Medicare for spinal surgery and the hospitals in our sample that self-identified in the questionnaire responses that they

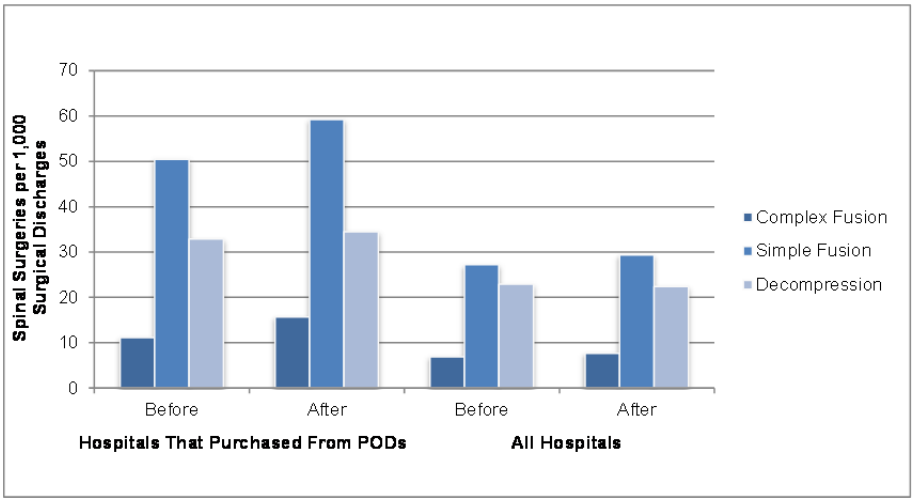
[16] In the questionnaire, we asked all 589 hospitals in our sample about their disclosure policies, regardless of whether they purchased from PODs. Overall, 60 percent of hospitals reported that they had policies in place to require physicians to disclose to the hospitals whether they have an ownership stake in medical device companies and 13 percent had policies requiring disclosure to patients.

purchased spinal devices from PODs.[17] We limit our consideration to these hospitals because they told us in the responses when they began purchasing from PODs. This analysis spans from FY 2004 to FY 2012.

The growth in the rate of spinal surgery after hospitals began purchasing from PODs was three times that for all hospitals

Hospitals' overall rate of spinal surgery—which includes spinal decompression only, spinal fusion, and spinal revision—grew more quickly for the group of hospitals in our sample that purchased from PODs. Before these hospitals started purchasing from PODs, they performed 95 spinal surgeries per 1,000 surgical discharges. This rate grew to 110 spinal surgeries per 1,000 surgical discharges after these hospitals began purchasing from PODs, an increase of 16 percent. Over matched time periods, the rate for hospitals overall grew by only 5 percent, from 57 to 60 spinal surgeries per 1,000 surgical discharges (see Chart 2).

Chart 2: Types of Spinal Surgeries Performed Before and After Hospitals Started Purchasing Spinal Devices From PODs



Source: OIG analysis of hospital questionnaire responses and the Medicare Standard Analytical File, 2013.

Furthermore, hospitals' rate of spinal fusions—surgeries that are more likely to use spinal devices—grew more than twice as fast among hospitals that used PODs compared to the rate for hospitals overall. The rate of spinal fusions among hospitals that used PODs increased by 21 percent (from 62 to 75 spinal fusions

[17] We excluded 17 of the 119 hospitals that self-identified that they used PODs from this analysis because we did not have claims data available for the periods before and after they began purchasing from PODs.

per 1,000 surgical discharges) compared to 9 percent at all hospitals (from 34 to 37 spinal fusions per 1,000 surgical discharges).

The complexity of hospitals' caseloads of spinal surgeries remained largely unchanged after they began purchasing from PODs

We used three measures to describe the complexity of hospitals' caseloads of spinal surgeries: the percentage of caseload that was spinal fusion, the percentage that was complex spinal fusion, and the percentage that was spinal refusion.

The complexity of the spinal surgery caseload at hospitals in our sample that used PODs shifted slightly after they began purchasing from PODs, but not across all measures. For example, the percentage of spine surgery (either simple or complex) that was spinal fusion shifted in favor of spinal fusions after hospitals began purchasing from PODs. Prior to hospitals' purchasing from PODs, spinal fusion and decompression-only accounted for 61 and 39 percent of their spine caseloads, respectively. After hospitals began purchasing from PODs, spinal fusion increased to 65 percent of their caseloads while decompression-only fell to 35 percent. For hospitals overall, spinal fusion increased slightly from 60 percent to 62 percent of their spinal caseloads over the same time periods. Examining growth in this measure also highlights the potential for increased device usage because spinal fusion, which fuses vertebrae together, is more likely to involve implanted devices than decompression-only.

Two other measures of complexity remained unchanged and decreased slightly, respectively, after hospitals began purchasing from PODs. The percentage of complex spinal fusion accounted for 14 percent of hospitals' spinal caseloads both before and after they began purchasing from PODs. At hospitals overall, the percentage of complex spinal fusion increased slightly, from 12 to 13 percent over the same time periods. The percentage of spinal refusion, which involves refusing a fusion that failed previously or fusing additional vertebrae after a previous surgery, decreased from 6 percent of spinal surgeries before hospitals started purchasing from PODs to 5 percent afterward. At hospitals overall, the percent of spinal refusion remained unchanged at 4 percent over the same time periods.

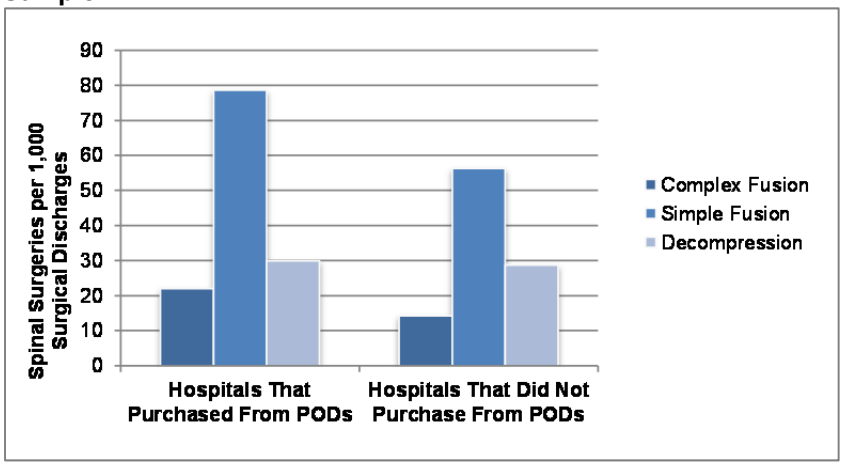
In FY 2012, hospitals in our sample that purchased from PODs performed more spinal surgeries than those that did not purchase from PODs

We compared hospitals' rates and caseloads of spinal surgery in FY 2012 between two groups of hospitals: the 203 hospitals in our sample that purchased from PODs and the 386 hospitals in our sample that did not purchase from PODs. For this analysis, hospitals that purchased from PODs included those that self-reported in the hospital questionnaire responses that they purchased from PODs and those we identified through our cross-referencing of data from the responses and invoice review.

Hospitals that purchased devices from PODs performed over a quarter more spinal surgeries than hospitals that did not purchase from PODs

Hospitals that did not purchase spinal devices from PODs performed 99 spinal surgeries per 1,000 surgical discharges in FY 2012. Hospitals that purchased spinal devices from PODs performed 28 percent more spinal surgeries, or 131 spinal surgeries per 1,000 surgical discharges (see Chart 3).

Chart 3: Type of Spinal Surgeries Performed in FY 2012 at Hospitals in Our Sample



Source: OIG analysis of hospital questionnaire responses, invoice review data, and the Medicare Standard Analytical File, 2013.

The complexity of hospitals' caseloads of spinal surgeries was slightly higher for hospitals that purchased devices from PODs than that for hospitals that did not purchase from PODs

On each of the three measures we used to describe the complexity of hospitals' caseloads, hospitals that purchased from PODs had a slightly more complex caseload than other hospitals.

First, hospitals in our sample that purchased from PODs performed more spinal fusion and less decompression-only surgery than hospitals that did not purchase from PODs. Spinal fusion made up 76 percent of the spinal surgery caseload at hospitals that purchased from PODs. It made up 69 percent of the caseload at hospitals that did not purchase from PODs. Conversely, decompression-only made up 25 percent of the spinal surgery caseload at hospitals that purchased form PODs and 31 percent of the caseload at hospitals that did not purchase from PODs.

The other measure of complexity that was slightly higher for hospitals that purchased from PODs was the percentage of caseload that was complex spinal fusion. At hospitals that purchased from PODs, complex spinal fusion made up 18 percent of the spinal surgery caseload compared to 16 percent at hospitals that did not purchase from PODs.

Our final measure of complexity, percentage of caseload that was spinal refusion, was similar between hospitals that purchased from PODs and those that did not purchase from PODs. Spinal refusion made up 7 percent of the caseloads at hospitals that purchased from PODs and 6 percent of the caseloads at hospitals that did not purchase from PODs.

CONCLUSION

PODs have a substantial presence in the spinal device market. PODs provided devices used in nearly a fifth of the spinal surgeries billed to Medicare in FY 2011, and over a third of the hospitals in our sample purchased spinal devices from PODs. Many of these hospitals began purchasing from PODs after 2009. Also, few hospitals in our sample required physicians to disclose their ownership in device companies, such as PODs, to their patients.

In FY 2012, hospitals that purchased from PODs performed more spinal surgeries and had slightly more complex spinal surgery caseloads than hospitals that did not purchase from PODs. After they began purchasing from PODs, hospitals experienced increased rates of growth in the number of spinal surgeries performed as compared to the growth rate for hospitals overall. Determining the cause for the increased rate of spinal procedures was beyond the scope of our review.

In addition, our findings raise questions about PODs' claims that their devices cost less than other suppliers. Within the device categories we examined, PODs' devices either cost the same as or more than devices from companies not owned by physicians. This, combined with the volume of spinal surgeries we found at hospitals that purchase from PODs, may increase the cost of spinal surgery to the Medicare program and beneficiaries over time. Further, hospitals inconsistently required physicians to disclose ownership interests in PODs to either the hospitals or their patients. Thus the ability of hospitals and patients to identify potential conflicts of interest among these providers is reduced.

The Sunshine Act may improve the ability of hospitals and patients to identify physicians' investment in device companies. The Act will require most PODs to report to CMS all physician ownership and investment interests.[18] CMS plans to list these companies and their payments on a publicly available Web site.

This report is being issued directly in final form because it contains no recommendations.

[18] 42 CFR§ 403.906.

APPENDIX A

Detailed Methodology

This study used Medicare claims and enrollment data, a review of the invoices for spinal devices implanted by a representative sample of spinal fusion surgeries billed to Medicare, and questionnaire responses from the hospitals that billed for Medicare for these surgeries.

Scope

This study is national in scope. For the purposes of this study, we defined "spinal surgery" as spinal decompression and spinal fusion. Our sample of claims included surgeries that involved a spinal fusion procedure and were billed to Medicare during FY 2011. We focused our sample on spinal fusion because surgeries involving these procedures were more likely to use implanted spinal devices than surgeries that involved only decompression. See Table A-1 for the complete list of procedures we used. We did not make any judgment on the legality of hospitals' relationships with PODs or on the appropriateness of spinal surgeries performed by surgeons.

Table A-1: ICD-9 Codes Used To Identify Spinal Surgeries

ICD-9 Procedure Code	ICD-9 Procedure Code Description
81.0 / 81.3	Spinal fusion/refusion
81.00 / 81.30	Spinal fusion/refusion, not otherwise specified
81.01 / 81.31	Atlas-axis spinal fusion/refusion
81.02 / 81.32	Other cervical fusion/refusion of the anterior column, anterior technique
81.03 / 81.33	Other cervical fusion/refusion of the posterior column, posterior technique
81.04 / 81.34	Dorsal and dorsolumbar fusion/refusion of the anterior column, anterior technique
81.05 / 81.35	Dorsal and dorsolumbar fusion/refusion of the posterior column, posterior technique
81.06 / 81.36	Lumbar and lumbosacral fusion/refusion of the anterior column, anterior technique
81.07 / 81.37	Lumbar and lumbosacral fusion/refusion of the posterior column, posterior technique
81.08 / 81.38	Lumbar and lumbosacral fusion/refusion of the anterior column, posterior technique
81.39	Refusion of spine, not elsewhere classified
81.62	Fusion or refusion of 2-3 vertebrae
81.63	Fusion or refusion of 4-8 vertebrae
81.64	Fusion or refusion of 9 vertebrae
84.51	Insertion of interbody spinal fusion device

Sample Selection

The sample universe for this file is all inpatient claims with discharge dates in FY 2011. We created our sampling frame by limiting the file to claims that reported one or more ICD-9-CM procedure codes for spinal fusion (see Table A-1 for the complete list of procedures we used). This resulted in population file of 127,547 claims for spinal surgery. From this file, we drew a simple random sample of 1,000 claims billed by 615 hospitals.

We used data from CMS's Certification and Survey Provider Enhanced Reporting (CASPER) database to get the name and address of each hospital in our sample and then forwarded these data to our Office of Investigations for review. As a result of this review, we removed 29 claims from 19 hospitals from our sample, leaving our data collection sample with 971 claims from 596 hospitals.

Data Collection

We administered the hospital questionnaire and asked hospitals to complete an invoice worksheet using secure Web-based survey software from November 2012 through February 2013. To initiate the data collection, we sent each hospital with a claim in our sample an invitation packet via a trackable delivery service. Each packet contained an invitation letter; a printed copy of the hospital questionnaire; a printed copy of the invoice review worksheet; detailed instructions, including a secure hyperlink and login credentials to the Web-based survey; and identifying information for the sampled claim(s) from that hospital. We made three attempts to obtain responses from hospitals. Of the 596 hospitals associated with claims in our data collection sample, 589 hospitals completed the questionnaire. These hospitals also provided invoice worksheet information for 963 of the 971 claims included in our sample.[19] Our overall response rate was 96 percent.

Hospital Questionnaire. We requested each hospital that billed for one or more spinal surgeries in our sample to answer a series of questions about the entities it purchases spinal devices from. We asked each hospital about its awareness of physician-ownership among its suppliers of spinal devices. In doing so, we differentiated between PODs owned by physicians practicing inside the hospital and those owned by physicians practicing outside the hospital. We defined physician-owners as those

[19] Five of the hospitals in our sample refused to provide invoice information detailing spinal devices implanted during eight inpatient stays covered by Medicare. We will refer these hospitals to CMS.

with a partial or full ownership stake through private investment, excluding stock in a publicly traded company.

If a hospital acknowledged purchasing from a POD, we asked it to identify the extent to which certain factors influenced its decision to purchase from a POD: cost savings on devices, quality of devices, clinical effectiveness, preference of surgeons, and additional services. We also asked whether PODs provided services to the hospital, including inventory management, operating room technical support, and coding assistance. We asked each hospital to estimate the date it began purchasing from a POD and asked that it identify the name and ownership structure (i.e., manufacturer, distributor, or unknown type of entity) of the POD(s) it purchased from. Finally, we asked whether the hospital was physician owned and asked about its policies on physician disclosure of ownership in medical device companies.

Invoice Review. We asked each hospital to complete a worksheet for each spinal surgery it had in our sample. To help hospitals identify each surgery, we provided them with the dates of admission from the claims and identified the beneficiaries treated with data from the Medicare Enrollment Database. The worksheet compiled detailed data about the spinal devices used for the surgery. These data included the number and types of devices implanted during the surgery and the price per device net of any manufacturer/distributor discounts or rebates. The worksheet also collected information about the entity that supplied the hospital with the devices, including what the entity's name was, whether the entity was a manufacturer or distributor, and whether the entity was a POD. We asked hospitals to substantiate the data they provided on the worksheet by sending us hard copies of supporting documents, such as invoices and purchase orders. In our analysis, we used only data substantiated by hospitals in this manner.

Pre-Test. Prior to our data collection effort, we pre-tested the hospital questionnaire and invoice review with four hospitals. We purposively selected one spinal procedure claim from each hospital and sent each hospital a test version of our invitation packet. We held a conference call with each hospital after it completed the pretest to discuss its experience with the questionnaire and invoice review and any recommendations for improvement that arose from the pretest. The pretest enabled us to improve our data collection instruments and gather data that informed our sampling plan.

Data Analysis

To determine the extent to which spinal surgeries used spinal devices provided by PODs and to determine whether the cost or quantity of spinal devices used in these surgeries differed for PODs, we used data from the invoice review. We supplemented the invoice review with data provided on the hospital questionnaire responses. Specifically, we cross-referenced PODs that hospitals reported in questionnaire responses to suppliers that hospitals reported on the invoice review to identify suppliers that hospitals may not have identified on the invoice review as being PODs. Our findings on spinal surgeries are generalizable to the population of surgeries involving spinal fusion and spinal revisions billed to Medicare during FY 2011.

To determine the extent to which hospitals associated with our claims sample purchased spinal devices from PODs, we used data from the questionnaire responses and the invoice review. We counted hospitals as purchasing from PODs if they self-identified as using PODs on the responses or invoice review or if we identified them through our cross-referencing of these two data sources. When hospitals reported publicly traded companies as PODs, we excluded those companies from our analysis. The responses identified 119 hospitals that reported purchasing spinal devices from PODs, and our cross-referencing identified a further 84 hospitals, for a total of 203 hospitals in our sample that purchased from PODs.

We also analyzed the questionnaire responses to learn why hospitals purchase spinal devices from PODs and determine the extent to which they have policies on physician disclosure of ownership in medical device companies. Our findings from this analysis are generalizable to the 119 hospitals in our sample that self-identified as using PODs in the responses.

To determine whether rates and complexities of spinal surgeries differed when hospitals purchased from PODs, we first categorized hospitals' spinal surgery claims by complexity of the surgical procedures reported on them. To do so, we used the ICD-9 procedure codes reported on the claims to classify them from least to most complex: decompression-only, simple spinal fusion, or complex spinal fusion. When the procedure codes on a claim reported multiple procedures, we classified that claim on the basis of the most complex procedure reported. For example, when a claim contained procedure codes for both decompression and simple fusion, we classified the claim as simple fusion. We also created a flag for increased complexity when simple or complex fusions were also spinal revisions (repeats or add-ons to prior fusion surgeries). We used these classifications to create rates by type of spinal surgery and three measures

to describe complexity of hospitals' spinal surgery caseloads: the percentage of caseload that was spinal fusion, the percentage that was complex spinal fusion, and the percentage that was spinal revision. We then conducted two separate analyses of hospitals' claims data.

Our first analysis compared the hospitals' caseload of spinal procedures performed before and after hospitals began purchasing devices from PODs. This analysis examined the rate and complexity of spine surgeries performed by hospitals that purchased from PODs in the sixth month before and in the sixth month after they began purchasing from PODs. As a comparison against these hospitals, we analyzed the spinal surgery caseload at all hospitals for the same before and after time periods. For example, if Hospital A started buying from PODs in March 2011, we calculated its rate of spine surgeries before it began purchasing from PODs using all spine surgeries performed by Hospital A in September 2010. We calculated the all-hospital rate using the rate of spine surgeries performed in September 2010, but across all hospitals, not only at Hospital A. Our findings from this analysis are generalizable only to the hospitals in our sample that self-identified as using PODs in the questionnaire responses and that also told us when they first began purchasing spinal devices from PODs. We excluded 17 of the 119 hospitals that self-identified that they used PODs from this analysis because we did not have claims data available for the periods before and after they began purchasing from PODs.

The second analysis compared the spinal surgery caseload during FY 2012 between the 203 hospitals in our sample that purchased from PODs and the remaining 386 hospitals that responded to the questionnaire. Similar to our first analysis, this analysis considered rate and complexity of surgeries for these two groups.

Limitations

This study relies on Medicare claims and the hospital questionnaire responses, which were self-reported by hospitals. We did not independently verify these data. Certain findings are limited to the hospitals associated with our sample of claims and are not generalizable. We describe changes in utilization rates over time, but did not determine the cause of those changes. We relied on ICD-9-CM procedure codes reported by hospitals on Medicare claims to determine the type and complexity of spinal procedures. We also did not assess the clinical benefits or equivalency of POD devices and non-POD devices.

Standards

This study was conducted in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX B

Confidence Intervals

Variable	Unweighted N	Weighted N	Point Estimate	95% Confidence Interval	
				Lower Bound	Upper Bound
Percent of Surgeries Using PODs Devices	926	118,109	18.8%	16.3%	21.3%
Mean Number of Devices Used					
For POD Surgeries	174	22,193	12.3	11.2	13.4
For Non-POD Surgeries	752	95,915	14.2	13.5	15.0
For POD Complex Spinal Fusion Surgeries	36	4,592	16.5	13.5	19.4
For Non-POD Complex Spinal Fusion Surgeries	187	23,851	23.0	20.8	25.1
Mean Total Device Cost					
For POD Surgeries	174	22,193	$11,601	$10,448	$12,754
For Non-POD Surgeries	752	95,915	$11,383	$10,705	$12,062
Mean Cost of Devices For POD Surgeries					
Spinal plates	82	90	$2,475	$2,183	$2,768
Other screws	91	293	$699	$602	$795
Interbody fusion devices, non-bone	95	128	$2,821	$2,455	$3,187
Pedicle screws	63	206	$942	$836	$1,048
Rods	74	110	$345	$232	$458
Cap/set screws	60	302	$142	$119	$165
Mean Cost of Devices For Non-POD Surgeries					
Spinal plates	251	263	$1,630	$1,477	$1,784
Other screws	883	2,806	$620	$589	$652
Interbody fusion devices, non-bone	376	476	$2,998	$2,820	$3,177
Pedicle screws	557	1,693	$892	$856	$928
Rods	544	871	$360	$340	$380
Cap/set screws	365	2,261	$148	$135	$162

Source: OIG analysis of hospital questionnaire responses and invoice review data, 2013.

APPENDIX C

Distribution of Sampled Surgeries by State

State	Number of Spinal Surgeries	Number of Surgeries Using POD Devices	Percentage of Surgeries Using POD Devices
California	76	24	32%
Florida	73	11	15%
Texas	65	19	29%
Georgia	44	8	18%
North Carolina	42	5	12%
Pennsylvania	39	9	23%
Michigan	38	4	11%
Ohio	37	6	16%
Missouri	34	11	32%
Illinois	28	5	18%
Minnesota	26	2	8%
New York	26	6	23%
Alabama	25	9	36%
Tennessee	25	4	16%
Virginia	25	4	16%
Oklahoma	23	6	26%
South Carolina	22	3	14%
Indiana	21	3	14%
Kansas	19	1	5%
Maryland	19	2	11%
Colorado	17	3	18%
Massachusetts	16	1	6%
New Jersey	15	0	0%
Washington	15	1	7%
Kentucky	13	1	8%
Louisiana	13	0	0%
Connecticut	12	0	0%
Arizona	11	1	9%
Idaho	11	3	27%
Nevada	11	6	55%
Arkansas	8	1	13%
Mississippi	8	4	50%
Oregon	8	0	0%
Wisconsin	8	0	0%
Iowa	7	0	0%
Nebraska	6	2	33%
South Dakota	6	3	50%
Utah	6	3	50%
Delaware	4	0	0%
Montana	3	0	0%
North Dakota	3	0	0%
New Hampshire	3	0	0%
Wyoming	3	1	33%
Alaska	2	0	0%
Hawaii	2	0	0%
Maine	2	0	0%
New Mexico	2	1	50%
District of Columbia	1	0	0%
Rhode Island	1	0	0%
Vermont	1	1	100%
West Virginia	1	0	0%
Total	**926**	**174**	**19%**

Source: OIG analysis of hospital questionnaire responses and invoice review data, 2013.

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office; Kenneth Price, Deputy Regional Inspector General; and Russell Hereford, Deputy Regional Inspector General.

Jesse Valente served as the team leader for this study, and Alyson Cooper served as the lead analyst. Other Office of Evaluation and Inspections staff from the Boston regional office who contributed to this study include Tim Chettiath, Melissa Hafner, and Elizabeth Havener. Central office staff who provided support include Clarence Arnold, Heather Barton, Berivan Demir Neubert, and Christine Moritz.

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.