

Physician Owned Distributorships:

An Update on Key Issues and Areas of Congressional Concern



A Senate Finance Committee Majority Staff Report

Physician Owned Distributorships:
An Update on Key Issues and Areas of Congressional Concern

TABLE OF CONTENTS

I. Overview.....	1
II. Legal Background.....	4
III. Summary of Committee Investigative Activities	5
IV. Recent Actions by Federal Agencies Since the Committee’s 2011 Report.....	7
A. HHS OIG 2013 Special Fraud Alert.....	7
B. HHS OIG 2013 POD Report.....	7
C. HHS OIG 2015 POD Memorandum	9
D. The Sunshine Act	9
E. DOJ Actions.....	10
V. Analysis of POD Utilization Rates	14
VI. Changes in PODs since SFA	16
A. National Spread of PODs	16
B. Effect of PODs on Pricing of Health Care Services	17
C. Changes in POD Payment Models.....	17
D. Changes in POD Compliance Efforts.....	18
VII. Industry Awareness and Risk Mitigation Strategies.....	19
A. Industry Executives’ Knowledge of PODs.....	19
B. Encouraging Innovation.....	20
C. Policies Implemented by Hospital Systems.....	20
D. POD Response to Hospital Policies	23
VIII. Conclusions and Recommendations	24

I. OVERVIEW

The Department of Health and Human Services Office of Inspector General (HHS OIG) has described physician owned distributorships (PODs) as “physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers.” Typically, the more hardware (screws, plates, and rods) that a physician implants, the larger the payment he or she receives from the POD. PODs can have widely varying payment structures, device disbursing methods, owner characteristics, levels of ancillary services provided, and compliance methods.¹ However, all PODs are structured to ensure that physician-investors profit from the sale and use of the POD’s products that they order for their own patients.²

To date, PODs have been most prevalent in the field of spinal surgery, and this report therefore focuses primarily on the influence of PODs within that medical field. However, the POD business model could be used to market any type of medical device, and there are indications that PODs have started to appear in other fields beyond spinal surgery. Many of the issues discussed in this report apply universally, and the Committee’s conclusions about PODs are therefore not limited to spinal device PODs.

Surgeons have a unique and powerful role in influencing both patient and medical practice decisions. When a surgeon recommends surgery, patients are strongly inclined to follow their doctor’s recommendation.³ Within the field of spinal surgery, spinal fusions are among the most serious and costly types of back surgery, and are typically only recommended for patients with the most serious back problems. Spinal implants are generally “physician preference,” meaning hospitals typically purchase the devices recommended by their surgeons. Spinal surgeons therefore have significant influence over both the frequency of spinal fusion surgeries and the devices used in those surgeries.

Unchecked, this position of power can give POD spinal surgeons the opportunity to grant themselves a steady stream of income by increasing the use of the products supplied by their POD. PODs present an inherent conflict of interest that can put the physician’s medical judgment at odds with the patient’s best interests.⁴

¹ The Committees’ concerns do not lie with physician ownership in general, but rather with ownership and other payment models used by PODs and their potential impact on physician behavior. The Committee supports physician-owned hospitals and other similar entities that comply with legal restrictions on physician ownership and payment.

² See section IV of the Committee’s 2011 report for a more descriptive analysis of various POD structures. Physician Owned Distributors: An Overview of Key Issues and Potential Areas for Congressional Oversight (June 2011), available at www.finance.senate.gov.

³ Medical professionals are among the most highly trusted professionals in the United States. Gallup, Americans Rate Nurses Highest on Honesty, Ethical Standards (Dec. 18, 2014).

⁴ Some PODs have implemented internal policies in an attempt to mitigate concerns about the inherent conflicts of interest that PODs present. These PODs argue that they are able to properly manage the conflicts of interest and are able to deliver cost savings to their hospitals. However, the fact that a POD has taken some steps to try to mitigate the risks associated with its business model does not mean that the PODs are operating in a legal or ethical manner.

Since the Committee's 2011 POD report, spinal implant PODs have continued to proliferate. The Committee's analysis revealed that as of November 2015, PODs are operating in at least 43 states. In 2013, HHS OIG issued additional guidance on PODs in the form of a Special Fraud Alert (SFA) and a report on the prevalence of POD-supplied spinal implants. In the SFA, HHS OIG called PODs "inherently suspect," a position it reiterated in its report. The 2013 SFA helped to inform the medical community of the dangers posed by PODs, and many hospitals and health systems have recognized these dangers and implemented policies to better govern their relationships with PODs, and as a result PODs are migrating to smaller and more rural hospitals.

HHS OIG found that the rate of spinal surgery grew three times faster for hospitals that purchased from PODs than for hospitals overall, and that devices purchased from PODs were not less expensive than non-POD supplied devices. Moreover, according to HHS OIG, PODs supplied the devices to 1 in 5 spinal fusion surgeries billed to Medicare in 2011. We believe that since 2011, this percentage has increased.

Some have alleged that the POD compensation structure results in POD surgeons performing more spinal fusions than their non-POD peers. If this claim is accurate, it would confirm that PODs influence physician behavior and suggest that POD surgeons are performing potentially unnecessary surgeries, thus endangering patients and inflating federal healthcare costs. As discussed in greater detail in Section V, the Committee undertook an extensive effort to determine if POD surgeons do, in fact, perform surgery at a higher frequency than non-POD surgeons. Our analysis found that:

1. POD surgeons saw **significantly more** patients (24% more) than non-POD surgeons.
2. In absolute numbers, POD surgeons performed fusion surgery on **nearly twice as many** patients (91% more) as non-POD surgeons.
3. As a percentage of patients seen, POD surgeons performed surgery at a **much higher rate** (44% higher) than non-POD surgeons.
4. In absolute number, POD surgeons performed **nearly twice as many** fusion surgeries (94% more) as non-POD surgeons.

These findings quantify, for the first time, the extent to which POD ownership influences the behavior of individual physicians.

In view of the findings summarized in this report, the Senate Finance Committee staff has six primary concerns about PODs:

1. As stated by the HHS OIG in the 2013 SFA, financial transactions involving PODs may violate the Anti-Kickback Statute, Stark Law, or both.
2. POD physicians face an inherent conflict of interest when they have a financial incentive to perform surgeries. This incentive may compromise a doctor's medical judgment and place financial incentives at odds with the best interest of the patient.
3. Overutilization may occur if physicians perform additional, more complex, or medically unnecessary surgeries to garner POD financial incentives. Analysis by the Committee and HHS OIG suggest that POD doctors are, in fact, overutilizing spinal

implant products. Such overutilization results in higher costs for the entire health care system, and particularly for Medicare.

4. As a result of potential conflicts of interest and overutilization, PODs compromise patient safety as patients receive high-risk treatment beyond what is medically warranted. Any unnecessary medical procedure increases the risk that the patient may be harmed. Committee staff has heard extremely troubling reports of POD surgeons performing revision surgery to replace previously implanted hardware with the same or nearly equivalent hardware sold by their own PODs.⁵ While surgeons may contend that they replace such hardware for purely medical reasons, they would receive a payout from installing the POD hardware. Our concerns about medically unnecessary services are especially acute in the case of seniors who, due to their age, are less physically capable of withstanding the rigors of complex, invasive spine surgery.
5. Despite increased guidance from HHS OIG, there continues to be confusion in the medical community as to the legality of PODs.
6. A lack of transparency surrounds the entire POD industry. There is little evidence that PODs are complying with financial disclosure requirements, making it difficult to determine who is in a POD, how many PODs exist, or where a particular POD is operating. Indeed, there is ample anecdotal evidence that some PODs are actively working to obfuscate their financial relationships with physicians to avoid reporting requirements imposed by both the Centers for Medicare & Medicaid Services (CMS) and the physicians' hospitals. As a result, it is more difficult for hospitals to identify which of their physicians are in PODs, thus inhibiting their ability to protect themselves and their patients.

At the conclusion of this report we make several recommendations to address these concerns.

⁵ Wall Street Journal, Taking Double Cut, Surgeons Implant Their Own Devices (Oct. 8, 2011).

II. LEGAL BACKGROUND

Three federal laws related to program integrity are particularly relevant when evaluating the legality of PODs.

The Anti-Kickback Statute (AKS) prohibits offering, paying, soliciting, or receiving anything of value to induce or reward referrals or generate federal health care program business. The prohibition applies not only to traditional forms of remuneration, such as cash payments, but also to indirect payments, which could include investment opportunities, especially when terms of the investment are extremely advantageous for a physician, or where the physician-investor has a financial interest in generating business for the company.⁶ Criminal, civil, and administrative remedies may be imposed for violations of the AKS. Changes to the AKS in 2010 clarify that any “claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act].”⁷

The Physician Self-Referral Law (42 U.S.C. § 1395nn), also known as the Stark Law, prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies. It also prohibits the designated health services entity, often a hospital, from submitting claims to Medicare for services resulting from a prohibited referral.

The Physician Payments Sunshine Act (Sunshine Act)⁸ requires manufacturers of pharmaceuticals, biologicals, devices, and medical supplies that participate in federal health care programs to report to CMS any “payment or other transfer of value”⁹ to physicians and teaching hospitals. The law also requires manufacturers and group-purchasing organizations (GPOs), of which PODs are a subset, to report ownership or investment interests of physicians (or immediate family members) to CMS. Under the law GPOs, and consequently PODs, must also report to CMS any payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year. The Sunshine Act requirements are intended to promote transparency and reveal potential conflicts of interest.

⁶ HHS OIG, OIG Advisory Op., No. 97-5 (Oct. 6, 1997); HHS OIG, Special Advisory Bulletin: Contractual Joint Ventures, 68 Fed. Reg. 23,148, 23,150 (Apr. 30, 2003).

⁷ 42 U.S.C. § 1320-a-7b(g).

⁸ 42 U.S.C. § 1320a-7h.

⁹ The Sunshine Act includes a list of exceptions to this requirement. For example, manufacturers that had less than 10 percent gross revenue during the fiscal year preceding the reporting year from covered products are only required to report payments or other transfers of value related to covered products, not all products. Additionally, some products are excluded from the reporting requirements, such as drug samples intended exclusively for distribution to patients. 42 U.S.C. § 1320a-7h(e)(10)(B); *see* 42 C.F.R. § 403.904(i).

III. SUMMARY OF COMMITTEE INVESTIGATIVE ACTIVITIES

Committee staff first began to examine PODs in February 2011 based on information provided by a surgeon who had been offered the opportunity to become an investor/owner in a POD. The model of the proposed business arrangement appeared questionable, and the surgeon was concerned that these types of arrangements were becoming more commonplace in the market. Based on the information provided from this initial contact, the Committee soon found other examples of PODs and POD-like structures. Together, these events raised a number of questions concerning guidance about what was and was not appropriate, and how these entities were being overseen to ensure they were operating legally and ethically.

In April 2011, the Committee was contacted by multiple whistleblowers who provided information about specific surgeons affiliated with PODs and the allegedly harmful surgeries performed on Medicare beneficiaries by those surgeons. Many of these surgeries appeared to have been done to maximize the amount of hardware utilized from the PODs where the surgeons were also investor/owners. All of these cases were referred to law enforcement, and some have resulted in legal action against the individuals involved.

Committee staff continued to gather information about PODs throughout the spring of 2011. By the end of the spring, the Committee had sufficient data to conclude that PODs were an emerging issue with the potential to cause harm both to the Medicare program and Medicare beneficiaries. As a result, in June 2011 the Committee issued a high-level report outlining the issues with PODs and describing the breadth and depth of the problem based on the Committee's research.¹⁰ The report concluded that in the absence of stronger enforcement guidance, these entities would continue to grow at a rapid pace.

After the release of its report, the Committee sent a letter to the HHS OIG asking whether the existing guidance it had issued to date was sufficient to address the rise in these types of entities. In response to the Committee's letter, HHS OIG stated that the guidance it had already issued was more than sufficient, and it did not think additional guidance was necessary. The Committee also sent a letter to CMS asking them to consider including PODs when finalizing its regulatory guidance with respect to implementation of the Sunshine Act. CMS's response indicated that it would address these issues in its final regulatory language. Indeed, the final regulations issued in February 2013 did include PODs among the entities required to report to CMS any ownership and investment interests that are held by physicians.

Since the release of the Committee's 2011 report, Committee staff have continued to examine the growth and development of PODs. To develop a reasoned perspective, Committee staff sought and received information from numerous healthcare entities, including physicians (both those who participate in a POD and those who do not), insurers, medical device manufacturers, state and federal government agencies, medical ethics boards, hospitals, and patients. Additionally, Committee staff spoke with representatives of several PODs and POD advocacy groups.

¹⁰ Physician Owned Distributors: An Overview of Key Issues and Potential Areas for Congressional Oversight (June 2011), available at www.finance.senate.gov.

On November 17, 2015, the Finance Committee held a hearing titled, “Physician Owned Distributors: Are They Harmful to Patients and Payers?” Chairman Hatch and Ranking Member Wyden issued the following joint statement prior to the hearing:

While the vast majority of doctors operate with the highest ethical standards, those with a vested stake in medical device distributorships raise a number of concerning questions about the physician's motivation in prescribing a procedure, as well as the overall cost to the health care system. When physicians have a financial incentive to recommend and perform a surgery, a potential conflict of interest can occur and jeopardize the health of patients. With this hearing, the Committee will have the opportunity to hear views on all sides of the debate, and we look forward to a constructive conversation on how to ensure major health decisions are made in the best interest of the patient and not the physician's pocketbook.

Witnesses at this hearing included Dr. Scott Lederhaus, M.D., President of the Association for Medical Ethics; Dr. John Steinmann, D.O., American Association of Surgical Distributors; Suzie Draper, Vice President of Business Ethics and Compliance, Intermountain Healthcare; and Kevin Reynolds, the son of a patient who was treated by a POD physician. Following the hearing, the Committee received additional information about PODs from stakeholders in the healthcare industry. Based on information provided to the Committee, the Chairman and Ranking Member also made a criminal referral to HHS OIG about a specific POD that may have been violating numerous federal laws.

After the hearing, it became clear that PODs are a significant concern for numerous members of the Committee, including the Chairman. We therefore expect that Committee staff will conduct additional oversight efforts following the release of this report.

IV. RECENT ACTIONS BY FEDERAL AGENCIES SINCE THE COMMITTEE'S 2011 REPORT

A. HHS OIG 2013 SPECIAL FRAUD ALERT

In March 2013, HHS OIG issued an SFA on PODs and potential violations of the AKS. SFAs are used by HHS OIG to notify the health care industry of certain abusive practices of which HHS OIG has become aware, and that it plans to prosecute, or pursue civil and administrative action against, as appropriate. SFAs are extremely significant warnings that HHS OIG only releases for particularly egregious issues, as illustrated by the fact that only five SFAs have been issued in the past 15 years.

The 2013 SFA highlighted the attributes and practices of PODs that HHS OIG believes create substantial risk of fraud and abuse and pose a danger to patient safety. In finding that PODs were “inherently suspect,” HHS OIG reiterated its “longstanding position that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute.”¹¹

The SFA describes the inherently suspect characteristics of PODs and provides a non-exhaustive list of factors that particularly concern HHS OIG. The OIG was “concerned when PODs, or their physician-owners, exhibit **any** of” the suspect characteristics.¹² As HHS OIG noted in the SFA and previous guidance, the financial incentives inherent in POD investment may lead to the corruption of medical judgment and overutilization. Overutilization leads to increased costs to the Federal health care programs and beneficiaries and unfair competition.

Although HHS OIG cited the proliferation of PODs and considered them inherently suspect under the AKS, it recognized “that the lawfulness of any particular POD under the anti-kickback statute depends on the intent of the parties.”¹³ The OIG noted that such intent is evidenced by a POD’s characteristics, safeguards, and conduct of the individuals involved.¹⁴ Because the AKS ascribes criminal liability to both parties in an impermissible kickback, hospitals and health care facilities that work with PODs may also be criminally liable under the AKS.

We fully support and agree with HHS OIG’s findings in the SFA and encourage distributors, physicians, compliance officers, and others to familiarize themselves with the SFA and align their behavior with it.

B. HHS OIG 2013 POD REPORT

In October 2013, HHS OIG issued a report entitled *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use*. This study was undertaken at the Committee’s request due to concerns about the growth of PODs and their potential adverse effects on both

¹¹ HHS OIG, Special Fraud Alert: Physician Owned Entities (Mar. 26, 2013).

¹² *Id.* (emphasis added).

¹³ *Id.*

¹⁴ *Id.*

Medicare beneficiaries and Federal health care programs. The study examined a random sample of 1,000 spinal fusion surgery claims submitted to Medicare in fiscal year 2011.

HHS OIG found that PODs held a substantial share of the spinal device market. In fiscal year 2011, PODs supplied the medical devices used in nearly one in five spinal fusion surgeries billed to Medicare. Surgeries performed with POD devices used fewer devices per surgery than surgeries performed with non-POD devices, but device costs for surgeries performed with POD devices were not lower than non-POD device costs, and in fact, one type of device supplied by PODs was more expensive. OIG concluded:

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.¹⁵

About one third of hospitals in the sample purchased spinal devices from PODs. Importantly, approximately 40% of hospitals that purchased from a POD did not realize that they were dealing with a POD. To the contrary, these hospitals indicated to HHS OIG that they were, in fact, *not* doing business with a POD. HHS OIG was only able to identify these POD relationships by cross-referencing hospital invoices against a list of PODs identified by other hospitals.

A majority of hospitals that purchased from PODs began this practice after 2005. HHS OIG found that surgeons had a large influence on hospitals' decision to beginning purchasing from PODs:

Ninety-four percent of hospitals that purchased from PODs reported that surgeon preference influenced their decision to purchase from PODs. ... Hospitals ranked surgeon preference over quality and effectiveness of devices as factors that influenced their decision to purchase spinal devices from PODs.¹⁶

Of the hospitals purchasing from PODs, about two-thirds reported that they purchased from PODs owned by physicians practicing in their hospitals. While 65 percent of POD purchasing hospitals had policies requiring physicians to disclose ownership stakes in device companies to the hospitals, only 8 percent required that surgeons disclose ownership stakes in device companies to patients.¹⁷ HHS OIG noted:

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.¹⁸

¹⁵ HHS OIG, *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use* (Oct. 2013).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

HHS OIG found that when the sampled hospitals began purchasing from PODs, their rate of spinal surgery grew three times faster than the rate for hospitals overall. In fiscal year 2012, sampled hospitals that purchased from PODs performed over 28 percent more spinal surgeries than those that did not purchase from PODs, and they also had a slightly more complex caseload.¹⁹

These findings are significant because they provided the first extensive, independent survey of the impact of PODs on doctor and hospital behavior. The HHS OIG's findings rebut many claims made by PODs²⁰ and show that PODs do not lower costs. To the contrary, PODs increase utilization rates, thereby increasing Federal health care costs. POD physicians can and do use their influence to have their hospital purchase from their POD. Furthermore, the lack of transparency surrounding PODs and reporting of physician ownership to hospitals and patients is troubling, and hospitals should undertake efforts to improve transparency.

C. HHS OIG 2015 POD MEMORANDUM

In August 2015, HHS OIG issued a memorandum entitled "Overlap Between Physician-Owned Hospitals and Physician-Owned Distributors." This memorandum examined the overlap between physicians who have ownership in physician-owned hospitals and PODs. HHS OIG was only able to identify one physician who had an ownership interest in both a POD and a physician-owned hospital. HHS OIG was critical of the lack of transparency surrounding PODs and noted that they continue to evaluate options for improving transparency. HHS OIG expressed optimism that the Sunshine Act may improve transparency for the POD industry and make it easier to identify physician owners.²¹

Overall, Committee staff has heard reports that some within the health care industry remain confused as to the legality of PODs, even after the SFA, guidance, and memorandum. There is no clear test to determine whether a POD is operating legally and ethically, which can leave a hospitals and physicians at risk for potential legal problems. As discussed below, hospitals are carefully navigating these issues, especially since DOJ's recent high profile cases against POD doctors.²²

D. THE SUNSHINE ACT

The Physician Payments Sunshine Act²³ requires pharmaceutical, biological, medical device and medical supply manufacturers of products that are covered under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) to report to CMS any payments made to physicians or teaching hospitals. Group-purchasing organizations (GPOs) must also report these payments to CMS. The goal of the Sunshine Act is to promote transparency and reveal potential conflicts of interest. Mandatory providers include all licensed physicians (dentists, podiatrists,

¹⁹ *Id.*

²⁰ In a nutshell, many PODs have argued that the physician-ownership model lowers costs of spinal fusion surgery by eliminating the cost of sales representatives, increasing competition, and enabling bulk purchasing.

²¹ HHS OIG, Memorandum Report: Overlap Between Physician-Owned Hospitals and Physician-Owned Distributors (Aug. 13, 2015).

²² Wall Street Journal, Surgeons Eyed Over Deal With Medical-Device Makers (July 25, 2013)

²³ 42 U.S.C. § 1320a-7h.

optometrists, etc.) and teaching hospitals. General payments, ownership or investment interests, and research payments must be reported. Any payments less than \$10 (unless payments total \$100 over the course of a year) do not need to be reported. Failure to report results in fines of \$1,000 - \$10,000 per unreported payments, up to an annual maximum of \$150,000. Deliberate failure to report results in \$10,000 - \$100,000 per payment, up to a maximum of \$1 million.

In February 2013, CMS released a final rule that explains how medical device and medical supply manufacturers must report payments or transfers of value they made to recipients.²⁴ The rule states that it applies to any GPO that “purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, **but not solely for use by the entity itself.**”²⁵ Consistent with the statute, this definition subjects PODs to Sunshine reporting requirements.²⁶ In discussions with the industry, CMS has explicitly confirmed that PODs are required to report payments under the Sunshine Act, and that PODs that neglect to report payments could face steep penalties for deliberately failing to report.

In the fall of 2014, CMS published the first batch of payment data on its Open Payments website, enabling users to search for and see the financial payments made to physicians. However, it appears that many PODs are not complying with the Sunshine Act requirements to report their payments or ownership interests to CMS. In examining the Open Payments data, Committee staff found only a few PODs that reported their payments to physicians and POD ownership interests. Conversely, many PODs that are known to the Committee do not appear at all in the Open Payments database.

Overall, it appears that there are serious gaps in Sunshine reporting of POD arrangements. These shortcomings prevent patients and hospitals from having access to information about the financial interests of physicians, which was the primary goal of the Sunshine Act. Possible steps to remedy these problems are explored in the conclusion to this report.

E. DOJ ACTIONS

DOJ has recently brought high profile cases that highlight the dangers and potentially illegal behavior of PODs. These cases revolve around Dr. Aria Sabit, a POD spine surgeon who practiced in California and Michigan, and Reliance Medical Systems, the parent company of Dr. Sabit’s POD. The Reliance ownership model appears similar to many other PODs that are currently operating. Although the discussion below focuses primarily on Dr. Sabit, actions brought under the False Claims Act against Dr. Sabit also include other physicians and Reliance employees.

In June 2009, Dr. Sabit began practicing at a California hospital. In May 2010, Sabit bought a twenty-percent ownership of a California POD named Apex Medical Technologies LLC (Apex),

²⁴ Transparency Reports and Reporting of Physician Ownership or Investment Interest, 78 Fed. Reg. 9458 (Feb. 8, 2013) (amending 42 C.F.R. Parts 402 and 403).

²⁵ 42 C.F.R. § 403.902 (emphasis added).

²⁶ See, e.g., Mintz, Levin, Cohn, Glovsky, and Popeo, P.C., CMS Publishes Final Sunshine Act Rule (Feb. 4, 2013). Even PODs that sell to only one hospital are subject to reporting, because such PODs are acting for a “group of individuals [the owner physicians] or entities [the hospital]” in “purchas[ing] or arrang[ing] for or negotiate[ing] the purchase” of covered products. 42 C.F.R. § 403.902.

following a brief trial period.²⁷ Dr. Sabit began using Apex's products in his surgeries, and the Wall Street Journal reported that the number of spine fusions Dr. Sabit performed increased by 57 percent following his investment in Apex.²⁸ Many of Dr. Sabit's spinal fusion patients had poor outcomes and faced serious complications following their surgeries. Two of Dr. Sabit's patients died and 28 others sued Dr. Sabit for medical malpractice.²⁹ In December 2010, Sabit was suspended from his hospital and soon thereafter both the FDA and California Medical Board began investigating Dr. Sabit.³⁰ The results of the FDA investigation were not made public. However, in August 2014, following the California Medical Board's investigation of Dr. Sabit for gross acts of negligence, Dr. Sabit settled his case and surrendered his California medical license.³¹

In the midst of these proceedings, Dr. Sabit relocated to Michigan in early 2011 and continued his spinal practice.³² In August 2012, Reliance Medical Systems, Apex's parent company, shut down Apex and discontinued their relationship with Dr. Sabit.³³ Dr. Sabit continued practicing until July or August 2014 and was arrested in November 2014 following an attempt to flee the country.³⁴

Dr. Sabit was indicted in two criminal complaints. In brief, the allegations against Dr. Sabit are as follows:

- The first criminal complaint charges Dr. Sabit with health care fraud under 18 U.S.C. § 1347 and unlawful distribution of a controlled substance under 21 U.S.C. § 841(a)(1). The complaint alleges that Dr. Sabit failed to implant instrumentation and perform fusions that he later billed to Medicare, and that he prescribed Roxicodone to a patient for no legitimate medical purpose.³⁵
- The second criminal complaint charges Dr. Sabit with conspiracy to commit health care fraud under 18 U.S.C. § 1349. It alleges that Dr. Sabit misrepresented to the hospitals where he practiced that he was in compliance with Medicare rules and the AKS, and further alleges that Dr. Sabit intentionally hid his involvement in an illegal kickback scheme, resulting in more than \$11 million of fraudulent Medicare claims being submitted.³⁶

Dr. Sabit is also a defendant in two False Claims Act civil cases brought by DOJ against Reliance, Apex, and others involved in the POD.

In May 2015, Dr. Sabit entered a plea agreement to resolve both criminal cases in which he plead guilty to four counts of health care fraud, one count of unlawful distribution of a controlled

²⁷ Wall Street Journal, Surgeons Eyed Over Deal With Medical-Device Makers (July 25, 2013).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ Wall Street Journal, Justice Department Sues Surgeon Aria Sabit Over Spinal Operations (Sep. 10, 2014).

³² Wall Street Journal, Detroit Neurosurgeon Aria Sabit Arrested for Alleged Insurance Fraud (Nov. 24, 2014)

³³ Wall Street Journal, Surgeons Eyed Over Deal With Medical-Device Makers (July 25, 2013).

³⁴ Wall Street Journal, Detroit Neurosurgeon Aria Sabit Arrested for Alleged Insurance Fraud (Nov. 24, 2014).

³⁵ Rule 11 Plea Agreement filed in U.S. v. Sabit, No. 14-20779 and 15-20311 (E.D. Mich. May 22, 2015).

³⁶ *Id.*

substance, and one count of conspiracy to commit health care fraud.³⁷ On October 2, 2015, Federal Judge Paul Borman rejected the plea agreement without explanation.³⁸ The court later asked for additional statements from victims of Dr. Sabit. As of the date when this report was issued, these criminal cases were still pending resolution.

Although the May 2015 plea agreement was not approved, the statements agreed to by Dr. Sabit illuminate the nature and extent of illegal activity engaged in by Apex. Dr. Sabit acknowledged the following facts:

[Dr. Sabit] conspired to commit health care fraud by submitting and causing the hospitals and surgical centers where [Dr. Sabit] performed spine surgeries to submit false and fraudulent claims to Medicare for items and services provided by [Dr. Sabit]. Specifically, every spine surgery that [Dr. Sabit] performed using spinal implant devices from Apex was predicated on illegal kickback payments that [Dr. Sabit] received . . . and [Dr. Sabit's] fraudulent representations that he was compliant with the Anti-Kickback Statute and Medicare's laws, regulations, and program instructions at the time [Dr. Sabit] provided the items and services and those items and services were billed to Medicare, in violation of Title 18, United States Code, Section 1349. Moreover, **incentivized by this illegal kickback arrangement and his involvement in the conspiracy, [Dr. Sabit] performed medically unnecessary surgeries that caused serious bodily injury to at least some of his patients.**

* * *

[Dr. Sabit's] involvement in Apex and the **financial incentives provided to him by the Apex Co-Conspirators and Apex caused [Dr. Sabit] to compromise his medical judgment** and abuse his position of trust as both a physician and a Medicare provider by performing medically unnecessary spine surgeries on at least some of the patients in whom he implanted Apex spinal implant devices. Motivated by the money that he made from using Apex Spinal implant devices, on a few occasions, [Dr. Sabit] referred patients in [California] and [Michigan] for spine surgery who did not medically need surgery or [Dr. Sabit] referred his patients for more complex surgeries, such as multi-level spine fusions.

[Dr. Sabit] also abused his position of trust as both a physician and Medicare provider by, at times "over instrumenting" his patients. Specifically, the financial incentives provided to [Dr. Sabit] by the Apex Co-Conspirators and Apex caused [Dr. Sabit] to use more Apex spinal implant devices in surgery than were medically necessary to treat his patients in order to generate more sales revenue for Apex.

[Dr. Sabit's] performance of medically unnecessary surgeries and his use of medically unnecessary Apex spinal implant devices resulted in him causing serious bodily injury to his patients. Specifically, at least some of [Dr. Sabit's] patients suffered extreme physical pain, protracted and obvious disfigurement, and protracted loss or impairment of the

³⁷ *Id.*

³⁸ Detroit Free Press, Judge Rejects Birmingham Neurosurgeon's Plea Deal (Oct. 2, 2015).

functioning of a body member as a result of [Dr. Sabit] selecting them for and performing surgery on them.³⁹

Following the submission of Dr. Sabit's guilty plea, Assistant Attorney General Leslie R. Caldwell said,

Doctors who sell their medical judgment and ethics for personal profit endanger the lives and safety of vulnerable patients who count on their advice to make life-altering decisions. The Criminal Division of the Department of Justice will continue to prioritize the prosecution of doctors whose criminal behavior puts patients at risk.⁴⁰

Indeed, POD physicians have been on notice about the illegality of POD arrangements for a long time, but these cases highlight law enforcement's willingness to prosecute doctors engaged in illegal activity. DOJ has also brought similar actions as part of its ongoing "Operation Spinal Cap," a concerted effort to go after individuals involved in illegal kickbacks for spinal surgery-related schemes. In late November 2015, DOJ announced charges against five individuals in a fraudulent referral and billing scheme that was part of "Operation Spinal Cap."⁴¹

Committee staff fully supports DOJ efforts to prosecute surgeons who put patients at risk for personal financial gain. We believe that DOJ's continued focus on these arrangements could persuade POD surgeons to sever their relationships with PODs and remind the health care industry that the POD business structure results in behavior that is unethical and potentially illegal.

³⁹ Rule 11 Plea Agreement filed in U.S. v. Sabit, No. 14-20779 and 15-20311 (E.D. Mich. May 22, 2015) (emphasis added).

⁴⁰ DOJ, Detroit-Area Neurosurgeon Admits Causing Serious Bodily Injury to Patients in \$11 Million Health Care Fraud Scheme (May 22, 2015).

⁴¹ FCA Update, "Operation Spinal CAP" Sees Former Hospital Executive, Physicians Charged for Their Roles in Kickback Scheme (Dec. 3, 2015).

V. ANALYSIS OF POD UTILIZATION RATES

Reports have suggested that POD doctors perform more surgeries than their non-POD peers. To evaluate these reports of increased utilization, Committee staff undertook an extensive effort to identify spinal fusion surgeons belonging to a POD, and then compare the number of surgeries performed by those surgeons to the number of surgeries performed by surgeons unaffiliated with PODs.

The starting point for our analysis was a comprehensive data set compiled by CBS News as part of an in-depth report.⁴² The CBS data contains information about the number and type of spinal fusion surgeries performed by each physician in the United States who billed to Medicare from 2011-2012. CBS developed the following profile of the average spinal surgeon (regardless of whether the surgeon was in a POD or not):⁴³

	Patients Seen	Patients Performed Fusion On	Percentage Of Patients Seen That Had Fusion	Total Fusions Performed
Average for all Physicians in CBS Dataset	651	43	7%	46

With the help of many sources, Committee staff identified a total of 507 surgeons believed to have a financial relationship with a POD.⁴⁴ Using this list, we used the CBS data to compare the surgical rates for physicians identified as having a financial relationship with a POD with those who were not identified as affiliated with a POD. Our key findings are summarized below:⁴⁵

	Patients Seen	Patients Performed Fusion On	Percentage Of Patients Seen That Had Fusion	Total Fusions Performed
Average POD Surgeon	677	55	9.1%	59
Average Non-POD Surgeon	547	29	6.3%	30

Although somewhat rudimentary, our analysis provides the first comparison of the utilization rates of POD surgeons with non-POD surgeons. We found that:

1. POD surgeons saw **significantly more** patients (24% more) than non-POD surgeons.
2. In absolute numbers, POD surgeons performed fusion surgery on **nearly twice as many** patients (91% more) than non-POD surgeons.
3. As a percentage of patients seen, POD surgeons performed surgery at a **much higher rate** (44% higher) than non-POD surgeons.

⁴² CBS, Tapping into Controversial Back Surgeries (Apr. 24, 2014).

⁴³ *Id.*

⁴⁴ Most commonly, POD-physician relationships were identified by a person in the health care industry with direct knowledge of the arrangement.

⁴⁵ Because the data provided was self-reported from individuals who have a potential interest in the outcome, our analysis does not follow standard statistical methods. However, we believe that these findings closely approximate the effect of POD ownership on spinal surgeon utilization rates.

4. In absolute number, POD surgeons performed **nearly twice as many** fusion surgeries (94% more) as non-POD surgeons.

Overall, we found that POD surgeons performed nearly 15 percent of spinal fusions billed to Medicare while making up only 8 percent of the total spinal fusion surgeons who billed to Medicare in 2011.

As troubling as our findings are, we believe that these numbers may understate the extent of POD penetration into the spinal fusion industry, as there has been growth in the number of PODs since the CBS data was compiled in 2011 and 2012. Our analysis validates the widespread belief that POD doctors see more patients, perform more surgeries, and perform more complex surgeries than their non-POD counterparts. As evidenced by Dr. Sabit's plea deal, our analysis reveals the extent to which financial incentives of PODs are overriding the medical judgment of some surgeons. These additional surgeries come at a cost, not only by increasing costs for the entire health care system, but also by harming patients who receive unnecessary treatment.

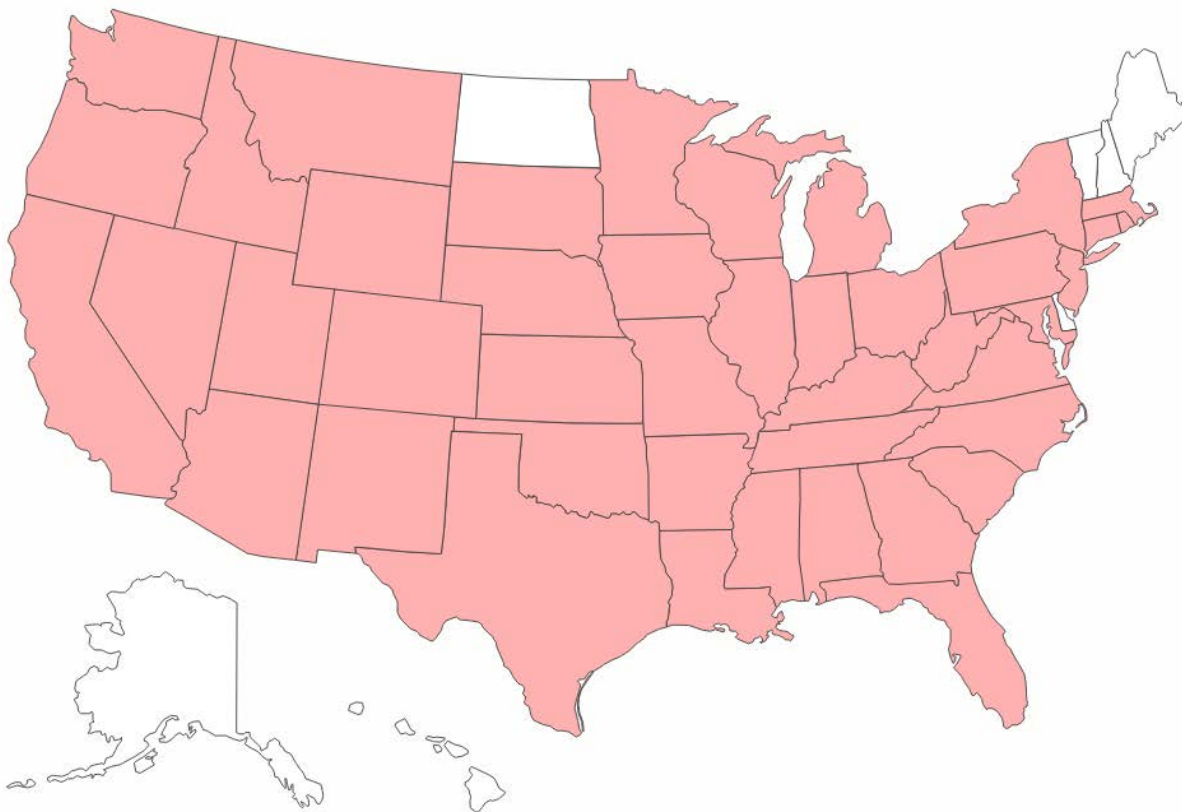
VI. CHANGES IN PODS SINCE SFA

A. NATIONAL SPREAD OF PODS

An important question is whether PODs have continued to spread throughout the country in recent years, particularly since the 2013 SFA. In order to evaluate the proliferation of PODs, the Committee asked various industry organizations to share their view of PODs in their communities.

The Committee has learned that since the 2013 SFA, the growth rate of PODs has slowed, but the absolute number of PODs does not appear to have declined. It appears that PODs are no longer concentrated in large hospital chains, many of which have adopted policies forbidding or strictly curtailing business with PODs. Perhaps to avoid strict compliance environments, PODs appear to be migrating to smaller and more rural hospitals, which have not yet developed POD-specific policies.

Overall, there is evidence that spinal device PODs are now operating across the country. In our 2011 report, the Committee identified 20 states where PODs were believed to be operating. The Committee now has reports of PODs operating in 43 states and the District of Columbia (states with a POD presence are highlighted in red).



The continued growth and spread of PODs is troubling, especially given the industry's increasing consensus and understanding of the dangers associated with PODs. Moreover, we have seen

indications that the POD business model may be spreading to other sectors of the medical industry beyond spinal surgery. The dangers and dubious legality of the POD business model are not constrained to spinal implants, and would apply to a POD operating in any segment of the health care industry. The Committee is particularly concerned about the POD model spreading to other types of medical implants, including hip, knee, and other joint replacements as well as in prosthetics and orthotics.

B. EFFECT OF PODS ON PRICING OF HEALTH CARE SERVICES

One effect of widespread POD penetration into the market for medical devices is that prices for related health care services may become distorted. Dr. Scott Lederhaus described this scenario in his written testimony submitted in advance of the Committee's November 17, 2015 hearing on PODs:

In addition to the severe ethical problems posed by PODs, they adversely affect competition and distort the true price of healthcare services. On the basic question of competition, PODs eliminate it. Because implants are physician preference items, once physicians invest in a POD, the hospitals and [ambulatory service centers] where they perform their procedures either buy from the POD, or the physicians will take their cases elsewhere. Direct sale from an implant manufacturer to the facility is eliminated.

Moreover, through what might be described as "Predatory Pricing," PODs prevent the non-POD doctors from being able to compete on a level playing field when it comes to contract negotiations with insurance groups. Physicians whose income is supplemented by their self-referral earnings from a POD can agree to what would otherwise be unrealistically low insurance reimbursement rates for their physician services. **Thus, the physicians who are members of a POD can simply eliminate competition between the POD and non-POD physicians by signing ridiculously low reimbursement healthcare contracts.** This rewards the POD physicians, stifles competition and has nothing to do with good or competitive care, but only about money. It can only hurt the market for health care services when inappropriate financial incentives hide the true costs that should be the basis for reimbursement rates and policies.⁴⁶

Indeed, through anecdotal evidence, the pressure that PODs have placed on specific U.S. markets is forcing non-POD doctors into the difficult position of losing business, or considering joining a POD.

C. CHANGES IN POD PAYMENT MODELS

It appears that PODs are changing how they organize and operate in order to hide their financial relationships with surgeons. First, an increasing number of PODs are reclassifying their surgeons as employees instead of physician owners in an attempt to avoid Sunshine reporting requirements.⁴⁷ Second, POD physicians are increasingly requesting that POD payments be paid

⁴⁶ Statement of Scott Lederhaus, M.D., President Association for Medical Ethics, submitted to Senate Finance Committee (Nov. 17, 2015) (emphasis added).

⁴⁷ The committee notes that the Sunshine Act exempts from reporting payments and other transfers of value to employees only when such payments are made by manufacturers, not GPOs, so that PODs that do not manufacture

to close family members or friends and not directly to participating surgeons. Third, while payments have traditionally been paid directly from the POD to the surgeon, some PODs are outsourcing all payments to a third-party who then pays the surgeon in an attempt to obscure the fact that the origin of the payment is a POD.

These changes in the payment structure of PODs are troubling, as it would appear that these practices are designed to circumvent laws designed to promote transparency, reduce conflicts of interest, and improve the health care system.

D. CHANGES IN POD COMPLIANCE EFFORTS

In response to HHS OIG's and DOJ's recent focus on PODs, some PODs have implemented internal policies in an attempt to mitigate concerns about the inherent conflicts of interest PODs possess. However, the fact that a POD has taken some steps to try to mitigate the risks associated with its business model does not mean that those risks no longer exist. Hospitals face serious risks when they do business with PODs, and the only way to completely eliminate those risks is to not conduct business with any POD or POD-like entity, and accordingly, many hospitals are implementing policies to strictly govern their relationships with PODs (*See Section VII(C)*). However, PODs are not going quietly into the night, and many hospitals face intense pressure from PODs to allow them to become and remain a hospital supplier (*See Section VII(D)*).

or take title to the devices they sell may not make use of the employment exception. 42 C.F.R. § 403.902. In addition, only payments to bona fide employees are exempt.

VII. INDUSTRY AWARENESS AND RISK MITIGATION STRATEGIES

A. INDUSTRY EXECUTIVES' KNOWLEDGE OF PODS

The Committee examined the results of a private two-state study examining the extent to which hospital executives, board members, and physicians were aware of PODs and the policies they had implemented to mitigate the hazards of PODs. The study had four main findings:

1. Stakeholder Knowledge of PODs

The study found that hospital executives, board members and physicians have extremely varied knowledge of PODs. Some individuals had no familiarity with PODs, while others had a comprehensive understanding of the issues and risks associated with PODs.

2. Stakeholder Attitudes Towards PODs

The study found that almost all individuals who were familiar with PODs had a negative attitude toward PODs. In addition, after educating those individuals with no familiarity of the issue, almost all commented that PODs present an inherent conflict of interest.

3. Key Risks Hospitals Perceive

The study found that hospitals identify three main areas of risk from PODs. The first is a financial risk, primarily because PODs create a risk that hospitals will not be reimbursed or have to pay back previously reimbursed money. The second risk was that of negative public perception and reputation. The conflict of interest associated with PODs can break the bond of trust between hospital and patient, compromise hospital and provider credibility, and hospitals could face heavy criticism and blowback from patients who disapprove of doctors profiting off their prescriptions. The third risk was that of legal action being taken against the hospital, including potential False Claims Act violations. Surveyors were told that since compliance is already a difficult process, the potential benefits of PODs do not justify the risks, so it is simpler and less risky for hospitals to not conduct business with PODs.

4. Hospital Policies on PODs

The study found an extremely wide variety of policies governing the relationship between hospitals and PODs. Some hospitals relied on their standard Stark Law and AKS rules, while others had strict rules forbidding business with PODs. There also were varying levels of enforcement for hospitals that had policies forbidding business with PODs. The hospitals that were most confident in their rules were those who had well-known no-POD policies, required that physicians attest they have no conflicts of interest, and had strict, up-front enforcement of their internal policies.

In addition to examining this study, we have spoken with the compliance officers of several hospitals about the complex compliance issues that PODs present. Among compliance officers who had heard of and understood the dangers of PODs, the primary concern was that despite the SFA and other guidance, the rules governing POD behavior remain murky at best. There is no clear test to determine whether or not a POD is behaving legally or ethically, which inhibits hospitals from being able to protect themselves from potential legal problems.

B. ENCOURAGING INNOVATION

Besides having to balance the demands of their surgeons with the legal liability, hospitals must also ensure that their policies encourage innovation and do not prevent their doctors from developing medical advances. Without a doubt, doctors are drivers of some of the most important medical innovations, and they play a unique role in being able to develop new processes, tools, and hardware to improve patients outcomes and advance medical science.

In order to promote innovation, hospitals must be able to recognize that certain physician ownership in legitimate innovator companies is allowable,⁴⁸ and to differentiate legitimate physician-owned businesses from problematic POD arrangements. Moreover, hospitals must be able to determine when a physician-owned business has created a product that is truly innovative, as opposed to repackaging an existing product with little or no functional improvement. To achieve these goals, health systems must ensure that their policies on physician ownership strike the right balance of preventing problematic POD relationships while allowing physicians to play a role, and be compensated in some fashion for, their important contributions to medicine.

C. POLICIES IMPLEMENTED BY HOSPITAL SYSTEMS

While we are concerned about some compliance officers' lack of familiarity with PODs, other hospitals are successfully implementing policies to mitigate the risks of working with PODs. Hospitals have implemented varied and unique strategies to protect themselves from PODs. Below, we highlight some examples of these policies.⁴⁹

ASCENSION HEALTH

Ascension Health prohibits its affiliates and Health Ministries from purchasing services and items from PODs that are either owned or controlled by one or more physicians. This prohibition includes pharmaceuticals, implants, instruments, and other devices. Ascension does not purchase or contract with PODs, either directly or indirectly.⁵⁰

⁴⁸ These companies are manufacturers who may have a relatively small portion of physician ownership (examples include physician ownership as a result of an initial capital investment, or development of new or innovative intellectual property) which generally diminishes as the company's products gain market acceptance. Unlike PODs, these companies widely market and sell their products to healthcare facilities where their physician owners do not practice, and in addition, physician owners' revenue is not tied to their referrals or usage of the company's devices.

⁴⁹ Inclusion or exclusion on this list does not imply the Committee's approval or disapproval of the policy. All hospitals should work closely with their legal and compliance departments to adopt a policy that works for their hospital.

⁵⁰ Ascension Health, Ascension Health's Position on Physician-Owned Distributors (July 29, 2013).

In addition, Ascension requires each supplier to sign a statement verifying that it “is not a POD and that it does not utilize PODs as distributors of products and/or services to our Participants.”⁵¹

HCA

HCA has a general prohibition on purchasing items from PODs except when the physician owners and their immediate family members are not on the medical staff of the purchasing hospital.⁵² Every vendor is required to complete a physician ownership and compensation form to explain the company’s ownership and compensation structure and HCA stores this information in a central database.⁵³ As part of that form, all vendors are required to read HHS OIG’s SFA and certify that they comply with the SFA and the AKS.⁵⁴

INTERMOUNTAIN HEALTHCARE

After HHS OIG issued the SFA, Intermountain Healthcare implemented a strict policy banning new orders from PODs and discontinuing recurring orders from PODs. The policy does not allow for any amount of physician ownership, and accounts for the various forms that ownership could take:

Under the Policy, a Physician Owned Entity (POE) includes any entity that is owned in any part by a physician or an immediate family member of a physician. There is no minimum percentage that needs to be reached to trigger the prohibition. “Ownership” can mean shares, partnership units, bonds and other forms of debt, or royalties based on purchases by the ordering physician.⁵⁵

An exception for medically disruptive technologies exists, but such exceptions must be approved by the Chief Executive Office, Chief Medical Officer, and General Counsel.⁵⁶ Intermountain also allows contracting with a POE “if no Physician owner . . . of the POE is in a position to generate business for Intermountain.”⁵⁷

When this policy was implemented, Intermountain sent a letter to its suppliers requesting an attestation that the supplier is not a POD (or POE). If Intermountain did not receive the attestation, Intermountain terminated any future purchases. Intermountain viewed false and incomplete attestations as a breach of the purchase agreement which could potentially result in disciplinary action.⁵⁸

⁵¹ Ascension Health, Position Letter Regarding Physician Ownership (July 23, 2013).

⁵² HCA, LL029 Prohibition on Purchasing Certain Products from Physician-Owned Businesses (July 1, 2014).

⁵³ HCA, LL027 Relationships with Physician-Connected Vendors (July 1, 2014).

⁵⁴ *Id.*

⁵⁵ Intermountain Healthcare, Letter on Intermountain Policy on Physician-Owned Device Companies (July 26, 2013).

⁵⁶ Intermountain Healthcare, Physician Owned Entities Financial Arrangements Policy.

⁵⁷ *Id.*

⁵⁸ Intermountain Healthcare, Letter on Intermountain Policy on Physician-Owned Device Companies (July 26, 2013).

LHP HOSPITAL GROUP

Following the SFA, LHP Hospital Group conducted its own internal inquiry into the spine manufacturers and vendors used by its hospital system. To mitigate the risk of PODs, LHP eliminated some suppliers, and LHP now has eight manufacturers which its spine surgeons can use for their implants.⁵⁹

PROVIDENCE HEALTH

Providence Health has a POD-specific policy that prohibits the purchase of items and devices from physician-owned vendors:

Providence will not purchase pharmaceuticals, implants, instruments or other medical devices if any purpose of the purchase is to generate or maintain referrals from a physician who has, directly or indirectly, a financial interest in the utilization of the item purchased.⁶⁰

Providence's policy does not prohibit professional service agreements and purchases from a manufacturer when a physician has sold intellectual property to that manufacturer. Rare exceptions are allowed, but must be approved by the Vice President of Supply Chain, the Chief Risk Officer, and the General Counsel.⁶¹

TRINITY HEALTH

Trinity Health has a supplier code of conduct that includes a section on PODs:

Trinity Health will not purchase or enter into agreements for the purchase of products or supplies, including, but not limited to pharmaceuticals, implants, instruments and other medical devices, from Physician-Owned Distributorships ("PODs") or similar entities that maintain ownership or investment interests held by physicians and/or immediate family members of physicians on the medical staff of a Trinity Health organization. Suppliers are required to disclose to Trinity Health any such ownership or investment interests in their companies.⁶²

We encourage hospitals to closely examine these and other risk mitigation strategies, compare them with their own POD policies, and take whatever additional steps are needed to improve their internal rules. Furthermore, we encourage hospitals to perform due diligence during their contracting process to enable early identification of POD suppliers.

⁵⁹ LHP Hospital Group, Approved Spine Manufacturers – Vendors (Aug. 18, 2014).

⁶⁰ Providence Health, Purchases from Physician-Owned Intermediaries-Distributors (Feb. 09, 2012).

⁶¹ *Id.*

⁶² Trinity Health, Supplier Code of Conduct.

D. POD RESPONSE TO HOSPITAL POLICIES

When hospitals implement new policies banning PODs as suppliers, they may experience strong pushback from their POD surgeons. Some may even threaten to leave the hospital system unless they and their POD are granted an exception. To illustrate the pushback that some hospitals have faced, we will briefly highlight the experience of one medium-sized health care system after they implemented a policy forbidding business with PODs, as described to the Committee.

Soon after the SFA was issued, the system took a conservative approach and implemented a policy forbidding business with all physician owned entities. The system had a large number of POD physicians, and many of them were critical of the new policy. Some even implied that they might leave the system unless the policy was changed or they were granted an exception. Nevertheless, the hospital system remained firm in its decision and uniformly implemented the policy. Over time, the physicians grew to accept the policy, and despite complaints, the hospital is not aware of a single instance in which a physician moved his or her practice from the system as a result of the system's POD policy.

Although this health care system was fortunate, others may not be able to retain all of their doctors when implementing a new physician ownership policy. Nonetheless, these policies are an essential step to complying with the law, so the possibility of losing physicians must be measured against the risks of noncompliance.

VIII. CONCLUSIONS AND RECOMMENDATIONS

The Committee remains highly concerned about the damage that PODs have done, and are continuing to do, to patient safety and federal healthcare programs. The dangers associated with PODs are becoming even clearer, and there is growing industry understanding and consensus surrounding the risks of PODs. Our own analyses and those of others leaves little doubt that POD financial incentives can and do alter surgeon behavior and result in a higher utilization rate by POD surgeons. Moreover, information provided to the Committee revealed that PODs have spread throughout the country and may be appearing in other areas of medicine beyond spinal surgery products. In some markets, PODs have become so engrained that they have distorted competition and pricing for medical devices, forcing doctors and hospitals who refuse to engage in illegal tactics into an untenable financial position. While the federal government and hospitals have taken actions to curb the impact of PODs in the spinal fusion industry, much remains to be done.

The following are the key findings of the Committee's investigation into PODs and recommendations on how to address some of the problems identified.

FINDING 1: LACK OF TRANSPARENCY

Federal law does not currently require disclosure of physician ownership directly to hospitals or patients. Hospitals and patients furthermore face many challenges identifying if physicians have a financial relationship with PODs. Overall, PODs operate in a very opaque environment and some PODs have taken steps to conceal their financial relationships.

Recommendation 1: Federal law should require physicians to disclose any ownership that they or their family members have in non-publicly traded device companies to the hospitals where they practice, and should also require disclosure to patients. Patients should also be notified and instructed of the implications and risks associated with physician ownership in device companies specifically including the risks of unnecessary procedures and patient harm.

Recommendation 2: CMS should require hospitals and ambulatory surgical centers to examine the Open Payments data collected under the Sunshine Act, and document that they have taken such data into account when making device purchasing decisions.

Recommendation 3: CMS and HHS OIG should examine whether current compliance guidance about PODs is sufficient, or if it should be supplemented in response to changes in the industry. In particular, consideration should be given to amending the HHS OIG compliance guidance for hospitals to recommend that hospitals adopt policies that would restrict dealing with PODs to circumstances that avoid any of the suspect characteristics identified in the OIG HHS SFA.

FINDING 2: PODS RESULT IN OVERUTILIZATION

When hospitals purchase products from PODs, the number of surgeries goes up, suggesting that some of the surgeries performed are medically unnecessary or overly complex.

Recommendation 1: GAO should examine the costs and benefits of CMS requiring hospitals that choose to purchase from PODs to perform enhanced quality assurance and utilization review activities in connection with surgeries using POD-supplied products.

FINDING 3: POD ILLEGAL BEHAVIOR

The business structure and payments associated with certain PODs have been found to be illegal. Furthermore, overt or implied threats made by physicians to move their practice unless a hospital accepts their POD would likely violate fraud and abuse laws.

Recommendation 1: Law enforcement should continue and expand their efforts to charge and prosecute those doctors, PODs, and hospitals that violate the law.

FINDING 4: HOSPITAL POLICIES

Many large hospitals and hospital systems have adopted policies to govern their relationships with PODs. However, many small hospitals do not have a POD-specific policy governing their interactions with PODs, and as a result PODs are migrating from large hospitals to small hospitals.

Recommendation 1: All hospitals should establish their own hospital-specific policies to manage their relationship with PODs consistent with the OIG HHS SFA and any further guidance to be promulgated by OIG under Finding 1/Recommendation 3. Hospitals should draft comprehensive policies to address PODs and should rigorously enforce them. CMS should establish a date whereby all hospitals must implement POD policies, and non-compliant hospitals should not be reimbursed for surgeries involving POD supplied devices until they have developed and implemented a POD-specific policy.

FINDING 5: PODS' CHANGING PAYMENT STRUCTURES

PODs have shifted to alternative payment structures in an attempt to circumvent the AKS and the Sunshine Act. Some PODs are declaring physicians to be employees rather than investors and having companies make payments to physicians under the name of a family member or friend.

Recommendation 1: CMS should undertake increased enforcement actions to ensure compliance with Sunshine Act reporting requirements. CMS and Congress should examine the benefit of increased penalties for intentional violations of the Sunshine Act. HHS OIG and law enforcement should investigate potential violations of the Stark Law and the AKS.

Recommendation 2: HHS OIG should study the impact of the SFA and recent litigation on PODs and update its 2013 report and SFA as needed. In particular, HHS OIG should consider whether the list of suspect POD characteristics in the SFA should be revised or expanded to account for developments since the SFA's issuance.

Recommendation 3: CMS should provide additional Sunshine Act guidance or rulemaking to make clear that the exception from reporting requirements for employment applies only to manufacturers (not GPOs), and only to bona fide employment, including standards that would preclude sham "employment" relationships from qualifying.