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

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

[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).

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]

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.

[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.

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).