

Physician Owned Distributors (PODs):

An Overview of Key Issues and
Potential Areas for Congressional Oversight



An Inquiry by the Senate Finance Committee Minority Staff
U.S. Senator Orrin Hatch, (R-Utah), Ranking Member

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I. Background

Earlier this year, the Senate Finance Committee minority staff began an inquiry into the complicated issue of physician owned distributors (PODs), also known as physician owned companies or intermediaries. Since that time, committee staff has reviewed over 1000 pages of documents, spoken to over 50 people and uncovered many issues associated with the PODs that merit further review and consideration. This report is a summary of the Committee findings to date and an overview of the key issues identified which have implications for the health care system as a whole.

II. Overview

Business arrangements involving physician ownership of medical device companies and distributorships have been around in various forms for at least ten years. The basic arrangement involves medical device companies formed to give physicians who control the choice of what medical devices they implant in patients a share in the profits generated by the sale of such devices. The physician owners can then use their ability to generate referrals for hospitals to induce them to buy the medical devices from the companies in which the physicians have ownership. In effect, these entities act as a middleman entity that exists to give its physician investors the opportunity to profit from the sale and utilization of the medical devices they provide to hospitals. This is a significant shift away from what has typically been the model for the supply chain in the implant world.

The Implant Supply Chain

Implantable medical devices historically have been sold almost exclusively to hospitals and surgery centers directly by manufacturers through representatives who may be W-2 employees or may be 1099 independent contractors (independent sales agencies which the industry calls “distributors”). The manufacturer and its representatives provide services to the institution along with the implants, including order and delivery, stocking and restocking, sterilization, selection, delivery and deployment of external instrumentation, and assistance to surgeons in the operating room. In this instance, the medical device goes directly from the manufacturer to the entity where it is being used as the hospitals and surgery centers are equipped to manage the safety of the devices.

The Difference with PODs

PODs step into this supply chain as a middle man entity with no obvious nexus other than ownership by the ordering/referring physicians. Many PODs lack any operating history or experience (except to the extent that they are organized by and outsource their functions to a third-party entrepreneur/manager), and may not offer any or most of the existing suite of services outlined above, but at best offer (usually through a third-party manager) to replicate some of the services already performed by the manufacturer and its representatives. PODs also differ from the physician-owned providers of ancillary healthcare services. For those arrangements, the Office of Inspector General for (OIG) for the Department of Health and Human Services has historically advised that following guidance like its Special Fraud Alert on Joint Venture Arrangements may chart a path to compliant operation, in that the service providers are subject to state licensure, federal regulation and public oversight that is currently lacking for PODs.

III. Proliferation of PODs

As physicians continue to see dramatic reductions in reimbursements, increased demands on their time, hospital cost initiatives and growth in patient and procedure volumes, they are continuously looking for sustainable ancillary revenue sources. This has led to numerous models being implemented by physicians to provide such revenue sources, but foremost among them in the surgical arena appears to be the PODs. These entities first appeared primarily in California beginning around 2003. Currently, they appear to be limited to the orthopedic implant (spine and total joint) sector of the device industry, but appear to be quickly branching out into other areas such as cardiac implant (e.g., pacemakers and defibrillators).

While originally there were a handful of PODs primarily based in Northern California which first brought this issue to the forefront, it is the rapid proliferation of the PODs over the past 18-24 months which has raised a number of concerns regarding the structure of the PODs. No longer are there just a handful of PODs which are all operated under an organized structure or that share similar characteristics. The lure of financial incentives and lack of regulatory oversight appears to be driving huge increases in the number of PODs so that they are now a significant national presence. To date, the Committee has identified at least 20 states with multiple PODs that appear to be operational. Over 40 plus PODs have been identified in California alone. In particular, there seems to be a marked increase in rural areas where the POD distributor model is being used very aggressively.

IV. POD Business Models

There are three primary POD business models that have emerged over the past few years:

- 1) The Physician Distributor Model where the POD functions as a product distributor that arranges to buy implants from manufacturers and resell the implants to the hospitals where the physician investors refer their patients for implant procedures;
- 2) The Physician Manufacturer Model where the POD claims to be an implant manufacturer with development of implantable product produced by an outsourced manufacturer and then distributed by the POD; and
- 3) The Physician Group Purchasing Organization (GPO) model where the PODs have organized in an attempt to take advantage of the anti-kickback “safe harbor” for GPOs. This potentially could allow for the POD to aggregate the buying power of a large number of members to negotiate lower prices from a wide variety of manufacturers.

There are many different structural twists on these models and the following are some of the many examples of the variations on the POD models identified by the Committee:

- 1) Every physician investor receives a percentage of the money that their surgeries generate for the POD;

- 2) Each physician investor is compensated equally, irrespective of his or her individual usage;
- 3) An individual physician investor's usage is carved out from the profits he or she receives, but receives profit from the other physician investors' usage;
- 4) The POD's product use is limited to procedures that are not federally reimbursable;
- 5) The POD is organized to sell devices designed by the physician investors;
- 6) The POD includes a shell, or second corporation/entity (i.e., a construction company), which is used to facilitate payment to the physician investors so as to avoid direct payment from the POD that is selling the products to its physician investors; and
- 7) PODs that span multiple states such that physician investors from each state only profit from physician investor usage in the other state.

The typical structure of a POD is that a small group of individuals, who may or may not be physicians, establish a company to manufacture or distribute medical devices for implantation in primarily orthopedic (as of right now) surgeries. The company then seeks investors, primarily physicians who can generate referrals that benefit the company. The physicians are then offered either partnership or ownership interests in the company in return for a cash buy in of anywhere from \$10,000 or more, and in return are promised the potential to earn returns at a far higher rate than they would get investing in more traditional investments. Numerous offering letters by some of these PODs obtained by the Committee present a compelling picture of the attraction of the POD to surgeon investors with claims of generous dividend returns of 25 percent or more, guarantees to increase patient load, and no real financial risk beyond the initial investment.

Most, if not all, of the products sold by PODs are sold to their own physician investors, and little or no business is obtained from physicians who have no affiliation with the POD. The business model is totally dependent upon hospitals agreeing to buy implants through the POD rather than directly from the manufacturer. This can be particularly troubling in instances where the physician investors of PODs are on the medical device or other related hospital committees that determine which products will be used at the hospital as physician could improperly influence the selection of a product in which he or she had a personal financial interest. The government, as evidenced by the "one purpose rule," has made clear that a physician's decision as to whether to use one product over another cannot in any way be based on the physician receiving payment for using a particular product. Therefore, even if the POD structure did lower healthcare costs, such an arrangement should not trump or justify violation of the anti-kickback statute or other Federal fraud and abuse laws.

All of the above models appear to be designed in a manner in which the physicians in the POD, in various levels of directness, profit from their use of the products they are selling. It may be possible to structure a POD that does not raise these issues and there appear to be some PODs that try to appropriately balance these competing interests. For example, if a POD was not permitted to do business with its own investors, their partners, or affiliated hospitals, presumably they would be acting as a traditional distributor and not be able to profit from their usage or the usage of other physician investors. However, even this structure would not prevent two separate PODs from using each other's products as a means to circumvent these rules.

V. Cost to the Federal Health Care Programs

One of the key assertions of the POD model is that they are lowering healthcare costs by providing products at a lower price than a medical device manufacturer or non-POD distributor. Opponents of the PODs claim this is a false metric because it does not take into account several critical and material factors in a true cost analysis, including the initial decision to operate on the patient and the number of revision surgeries necessary. Either of these factors could have a significantly larger impact on total healthcare costs in addition to calling into question whether it is in the best interest of the patient.

Proponents of the POD argue that the model allows them to engage in arms-length negotiations with the device manufacturer to secure a price for the product, which is usually lower than that which is offered to other purchasers, including hospitals. The POD is then able to share any savings with hospitals in which the device is eventually used. The POD is able to negotiate lower pricing because the manufacturer arguably then does not need to spend time or effort marketing its products. A POD in California has asserted that these savings are substantial and they issued a paper at the American Association of Orthopedic Surgeons annual meeting in 2009 which asserted that its model helped save the hospital they were affiliated with 34 percent over a two-year period on the purchase of implantable devices, with total savings over one million dollars.

The very nature of PODs seem to create financial incentives for physician investors to use those devices that give them the greatest financial return and that, in the process, patient treatment decisions may be based on personal financial gain. This is especially troubling given numerous concerned allegations provided to the Committee that, due to their financial interest, physician investors in PODs may perform more procedures than are medically necessary or may use implants of inferior quality or that are not best suited for the procedure. One surgeon provided examples to the Committee of elderly patients in a POD area who were receiving eight to ten fusions in their back despite the serious health risks posed by these procedures. Another example was of an elderly patient who had a herniated disc and ended up receiving four fusion operations based on the recommendation of their surgeon who happened to be a member of a POD. Other surgeons provided examples of patients who had died from multiple operations.

Ancillary evidence concerning the rise in utilization of spinal fusion surgery and the costs of those surgeries seem to have an interesting correlation to the timeframe in which PODs have begun to become a more prevalent business model. A study published last April in the Journal of the American Medical Association cited a 15 fold increase in the number of spinal fusion surgeries for Medicare patients from 2002 to 2007. This same study went on to say that “it is unclear why more complex operations are increasing. It seems implausible that the number of patients with the most complex spinal pathology increased 15 fold in just six years. There is, however, a significant financial incentive to both hospitals and surgeons to perform the complex fusions and that may play a role.”

One example provided by the Quality Implant Coalition showed an example at one hospital based, on an analysis of its claims data, which showed that spinal fusion revision rates increased over 300 percent after a POD spinal product distributor moved into the hospital's

area. That example was based on data from 2007, but numerous other anecdotal examples have alleged similarly dramatic increases in utilization after PODs entered the market, despite normal spine fusion procedure volume remaining constant. These actual and perceived increases raise significant questions of whether the physician investors decided to “re-do” a previously performed spinal fusion to utilize the POD’s products, thereby increasing POD revenue and physician return on investment. This is of particular concern as it raises serious patient safety and ethical questions, not to mention potentially increasing Medicare and other health insurer costs.

VI. Implication of the POD Model on Hospitals, Physicians and Device Manufacturers

With the POD structure, the surgeon is acting as the seller, buyer, and person making the decision about what is best for the patient. On its face this appears to be entirely inconsistent with the fundamental tenets of healthcare compliance that have shaped the medical device industry over the last decade, and the POD structure has generated significant conflict of interest and anti-kickback concerns. However, in the absence of more clearly articulated guidance on the legality of these arrangements, those affiliated with this aspect of the medical device industry are faced with walking away from a significant amount of business that will be absorbed by companies who are willing to engage in this practice, or acquiesce to the POD structure that, in many cases, is potentially unethical and/or illegal.

Currently, there are two major national law firms that have weighed in significantly on the POD issue and they have come down squarely on opposite sides of the issue. Hooper, Lundy & Bookman, P.C., has been the most vocal proponent of the POD model arguing that the increase in these models has been because of “demonstrated savings to hospital customers alongside favorable returns on investment for physician and non-physician investors in such companies.” They have opined at great length on the structure that they assert PODs must follow to make sure they are minimizing their regulatory risks and operating within the parameters of the federal fraud and abuse laws.

Conversely, Hogan Lovells (formerly Hogan & Hartson) has issued an extensive number of opinions articulating their analysis of why the POD models do not and cannot fit within the current fraud and abuse laws. Their view is that “we do not believe that physician ownership of physician owned intermediaries (POIs) reflect legitimate investments, and the evidence is that government fraud and abuse enforcement officials share our view. In fact, we believe close examination would reveal that most POIs essentially are shell entities, with no real infrastructure or capital investment, that have been developed for the unlawful purpose of directing remuneration to physicians for their ability to control the selection of surgical implants sold through the scheme. Moreover, unlike legitimate distributors and GPOs, POIs present an obvious and unavoidable potential for the patient and program abuses that the federal anti-kickback statute was specifically intended to prohibit.”

It appears that hospitals and physicians, like medical device manufacturers, would benefit greatly from clear legal guidance regarding doing business with PODs. The most consistent comment from individuals interviewed by the Committee on this topic was “it was unclear to them if PODs were legal or illegal.” As a result, potential physician investors typically choose the legal theory that best supports their inclination to join or refrain from joining a POD entity.

This lack of clarity seems to be the vastly disparate legal interpretations posited regarding PODs cited above and OIG's limited guidance on this issue to date.

In the absence of clarity, hospitals are in a position in which surgeons, who work in their hospital, generating income for the hospital, are approaching the hospital as a supplier and claiming that they are lowering healthcare costs by offering a lower price for products. This model seems inconsistent with the concepts of fraud and abuse law to think that a hospital can enter into a contract with their own physicians to purchase products that the hospital is paying for and that the physicians are selling and using. Hospitals, like manufacturers, have a responsibility to navigate their relationships with physicians with integrity such that a physician's ability to make more money based on the selection of products used does not enter into the equation of what is in the best interest of the patient. This obligation is greatly complicated by the threat of physician investors in PODs to take their practice and patients to another hospital if the hospital does not do business with them.

VII. Office of Inspector General Guidance

The OIG issued written guidance on this issue in 2006 expressing the need for careful review of these types of entities because of "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" which necessitates these arrangements being "closely scrutinized under the fraud and abuse laws." Additionally, in Congressional testimony two years later, an Office of Inspector General (OIG) representative articulated ongoing concerns that "physician ownership of medical device manufacturers and related businesses appear to be a growing trend in the medical device sector. These business ventures raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device."

Combined, these appear to express strong concerns from OIG that a physician's financial interest in physician-owned implant supply chain companies, including PODs, could influence inappropriately the physician's choice of implantable medical device or the facility where s/he will perform procedures. Despite this expression of concern, there is abundant evidence, as noted above, that PODs have proliferated greatly in the last several years. This proliferation may have been enabled by the absence of policy statements, guidance, or visible enforcement proceedings that demonstrate with sufficient clarity and emphasis the extent of the government's concerns with the ways that PODs differ from physician joint ventures to provide legitimate (and regulated) health care services, the risks of abuse posed by PODs, and inherent suspicions about whether they serve any legitimate value.

A consistent theme among the multiple individuals interviewed by the Committee was that while OIG has acknowledged the risks of abuse that PODs pose, the lack of any recent or more specific guidance on this topic has allowed these entities to flourish as a result by citing that they are indeed following the basic guidance set forth by the OIG. This guidance does not appear to address all of the new permutations of the POD model and many of the models are being set up in such a way to purposefully circumvent the federal fraud and abuse laws designed to curb such behavior.

VIII. **Physician-Payment Sunshine Law Implementation**

It does not appear that the legislative history of the Sunshine Law fully contemplated the POD concept. However, the POD model at its basic level appears to be exactly the type of entities envisioned by the drafters of the Sunshine Law, which would require disclosure of the financial interests of their physician investors. Therefore, the Centers for Medicare & Medicaid Services (CMS) needs to closely examine the physician ownership and investment interests presented by PODs and ensure that those are addressed as they finalize the reporting requirements of the Sunshine Law. This would mean that the distribution model of these physician owned companies would need to be included as CMS develops a final definition of “applicable manufacturers” and “applicable GPOs.” This would ensure consistent treatment of the three business models (physician-owned manufacturers, GPOs and distributors) that present similar policy and legal risks.

IX. **Accountable Care Organizations**

Another facet of the growth in PODs which needs to be taken into consideration is the extent to which the recently released Accountable Care Organization (ACO) regulations issued by CMS will provide an inadvertent loophole allowing the less reputable POD models to fall under the Stark and anti-kickback law waivers envisioned for ACOs. As such, it seems clear that CMS should take into account the POD models when developing the final ACO regulation to ensure that qualification and oversight of ACOs should protect against the abuses posed by PODs. The final rule should prohibit ACOs from purchasing products or services from entities that are owned by physicians participating in the ACO. Ownership would be deemed to exist if the physician receives any remuneration from the entity supplying the product or service. It should also be made clear that waivers of Stark and Anti-Kickback laws should not extend to PODs except where appropriate.

X. **Conclusion**

A number of legal and ethical concerns have been identified as a result of this initial inquiry into the POD models. The apparent lack of clear guidance from the government on this topic appears to be contributing to the potential for abuse in this area and it seems incumbent upon Congress to play a leadership role in bringing these issues to the forefront so they can be fully vetted and addressed. As such, the Committee is recommending that letters be sent to both OIG and CMS articulating many of the concerns cited above. We believe it is incumbent upon the Committee to work with OIG to address this rapidly evolving healthcare market issue by conducting an inquiry into PODs and their current structures and activities and develop recommendations for further action to effectively address the patient and program risks presented by PODs.