HOGAN & HARTSON

Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
+1.202.637.5600 Tel
+1.202.637.5910 Fax

www.hhlaw.com

Physician-Owned Intermediaries in the Medical Device Industry: The Case for Government Scrutiny Under the Federal Fraud and Abuse Laws

This paper has been prepared by Hogan & Hartson in response to information gathered from various firm clients and others regarding the growing – and we believe improper – influence of physician-owned intermediaries in the medical device industry. A physician-owned intermediary, or "POI,"[1] essentially is a middleman entity – typically organized in the guise of a product distributor or group purchasing organization (GPO) – that gives its surgeon-investors an opportunity to receive profits from the sale of certain medical devices to hospitals. At present, POIs appear to be focused in the cardiac implant (e.g., pacemakers and defibrillators) and orthopedic implant (e.g., artificial hips, knees and spinal products) sectors of the device industry, where they have the significant potential to influence implant selection. Because of the nature of cardiac and orthopedic implants, a substantial portion of the patients receiving these products through POIs likely are Medicare beneficiaries.

Simply put, we do not believe that physician ownership of POIs reflect legitimate investments. Rather, we believe a close examination will reveal that most POIs essentially are shell entities, with no real infrastructure or capital investment, that exist 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. In particular, we have concerns that:

- Physician ownership of POIs creates a conflict of interest that can distort medical decision making because it gives physicians an incentive to order the implants that will benefit them financially, rather than to choose the products that are best for their patients.

- In contrast to the hospitals who actually purchase the devices, the physician-owners of POIs have no countervailing incentive to keep costs down, so that physician ownership of POIs is likely to lead to higher prices. In the case of a POI-distributor, for example, the incentive is to get the lowest price possible from the manufacturer and to resell at the highest price possible to hospitals. And in the case of a POI-GPO, which is paid by manufacturers based on a percentage of purchases, a surgeon-owner ordering implants for

[1] POIs also are sometimes referred to as "POCs" or physician-owned companies.

his own patients has a direct financial incentive to choose more, and more expensive, products.

- Finally, POIs have an unfair effect on competition because hospitals who want a physician-owner to perform procedures there, and manufacturers who want those physicians to use their products, will have little or no choice but to deal with a referring physician's POI, even if it is more expensive to do so and even if the entity is not as well-qualified as its competitors.

In October 2006, the Office of Inspector General of the Department of Health and Human Services (OIG) indicated it was "aware of an apparent proliferation" of POIs and stated that "[g]iven the strong potential for improper inducements between and among physician investors, the entities, device vendors, and device purchasers," the OIG believed "these ventures should be closely scrutinized under the fraud and abuse laws."[2] More recently, OIG officials indicated in Congressional testimony that POIs "raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device."[3] Yet, while the Centers for Medicare & Medicaid Services (CMS) has considered amending its Stark physician self-referral regulations to address POIs more specifically,[4] no new regulatory restrictions have been adopted to date and no other meaningful government scrutiny of this business model has taken place. Thus, in the absence of government action, the financial appeal of this business model is proving irresistible to a growing number of physicians, with the result being that POIs are continuing to proliferate and may eventually become the dominant players in choosing medical devices. Although the effect of this trend will be experienced most immediately with cardiac and orthopedic implants, there is no reason to believe that other product areas will not be affected.

Given the serious fraud and abuse risks presented by POIs, we believe that further government inquiry into the *bona fides* of these entities is essential to protecting the integrity both of the Medicare program and of the U.S. markets for cardiac and orthopedic implants. To help guide those efforts, we set forth below (1) a more detailed description of the most common types of POIs that our medical device manufacturer clients are encountering, (2) the legal case for how these entities implicate, and most likely violate, the federal anti-kickback statue and the Stark

---

[2] Letter from Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General (Oct. 6, 2006), *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf.

[3] Testimony of Gregory Demske, Assistant Inspector General for Legal Affairs, before the U.S. Senate Special Committee on Aging Examining the Relationship Between the Medical Device Industry and Physicians (Feb. 27, 2008), *available at* http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

[4] Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare Program; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23528, 23695 (April 30, 2008) ("we are soliciting public comments as to whether our physician self referral rules should address POCs and similar physician owned companies more specifically"); *see also* Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare Program; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 48434, 48727 (Aug. 19, 2008) ("we are not adopting the position that physician owned implant or other medical device companies necessarily 'perform the DHS' and are therefore an 'entity'" under Stark, but "[w]e may decide to issue proposed rulemaking on this [POI] issue in the future").

physician self-referral law, (3) the patient and program abuses inherent to the POI business model, and (4) how the claimed benefits of POIs are illusory and merit investigation.

1. Types of POIs

From our experience, there appear to be three types of POIs: purported distributors, purported manufacturers, and purported GPOs. All are inherently abusive because they give rise to a fundamental conflict of interest that places the physician's financial interest in conflict with the patient's best interests. As the founder of one prominent POI baldly acknowledged in describing his own motivations, the essential business concept underlying a POI is "to form a limited liability company that consisted of approximately one hundred doctors who would also serve as the company's customer base."[5]

A. Distributor POIs

It appears that most POIs have organized themselves to function as product distributors that arrange to "buy" implants from manufacturers and "resell" the implants to the hospitals where the physician-investors refer their patients for implant procedures.[6] While most prescription drug products are sold this way in the United States (i.e., through distributors that buy and resell to pharmacies and other providers), sale through a distributor is uncommon in the medical device industry, and almost unheard of with implantable devices.[7] Rather, implant manufacturers overwhelmingly sell direct to the hospitals and surgery centers where patient procedures are performed. Though some end users keep product on consignment, due to the difficult task of keeping implantable devices sterile throughout the shipping process and the associated cost of storing unordered product, most sales are direct shipped from the manufacturer to the hospital in response to a specific order from a physician who plans to implant the product into his or her patient.

---

[5] *See, e.g.,* Declaration of Souhail Toubia in Support of Application for TRO, *Allez Medical Applications, Inc.* v. *Allez Spine*, Case No. 06CC0153, Cal. Sup. (April 17, 2006).

[6] In some instances, the POIs might not even buy and resell, but instead might receive some sort of "commission." Either kind of POI presents the same basic fraud and abuse issues.

[7] Most medical device manufacturers contract to some extent with independent businesses to serve as commissioned sales representatives. While the term in the industry applied to these representatives agents is "distributors," they are not true distributors, in that they do not buy and resell. Sales still go directly from the manufacturer to the hospital. Representatives of these independent businesses function like manufacturer-employed allied health professionals, assisting with ordering and distribution, supplying instrumentation for use in procedures, and in many cases assisting physicians during procedures in the operating room. *See, e.g.*, American Medical Association Council on Ethical and Judicial Affairs, Report on Industry Representatives in Clinical Settings (CEJA Report 2-A-07), *available at* http://www.ama-assn.org/ama/pub/category/3840.html ("Manufacturers of medical devices may facilitate their use through representatives . . . who can play an important role in patient safety by providing information about the proper use of the device or equipment as well as technical assistance to physicians"); *see also* American College of Surgeons, Statement on Health Care Industry Representatives in the Operating Room (ST-33, Revised September 2005), *available at* http://www.facs.org/fellows_info/statements/st-33.html (recommending hospitals adopt procedures to govern the conduct of "health care industry representatives" in the OR); Hayes et al., *The Role(s) of the Industry Employed Allied Professional*, 24 PACE 398 (March 2001). POIs typically do not employ allied health professionals, and do not provide any of these services to their physician and hospital customers.

In practical terms, this means that most distributor POIs likely do *not* actually acquire and take physical possession of the devices they sell. Thus, these arrangements require virtually no investment capital to get up and running. In addition, unlike legitimate manufacturers and their independent sales agents, distributor POIs typically do *not* offer the assistance of industry-employed allied health professionals.[8] Rather, these POIs have as their only substantive function procuring and entering into contracts for the sale of devices with hospital customers – a function which often is performed not by the POI itself, but by the organizers of the venture through a management contract relationship with the POI entity. Moreover, by virtue of their physician owners being able to leverage their hospital admissions into POI contracts, the POIs are engaged in "white coat" marketing by physicians, with all of the potential abuses that entails,[9] and can generate business for themselves via owner referrals for procedures involving POI-provided products.

Thus, distributor POIs provide no real value other than adding costs to the production cycle. They function as nothing more than contractual middlemen, providing a vehicle for their owners to take a mark-up on implant sales that the physician-owners order for their own patients. The economic incentive in such an arrangement is to buy the cheapest possible products and sell them to hospitals at the highest possible price, thereby maximizing the returns available to the referring physician-owners. Even if such POIs were to offer lower prices, there still would be no economic justification for the physician markup since the physicians are not contributing real capital, expertise, manpower or other functions for which legitimate business ventures typically are formed.

B. Manufacturer POIs

Some POIs use a business model in which they purport to be implant manufacturers. In most of the instances of which we are aware, these purported manufacturers are in fact nothing more than a distributor (as described above) that outsources all of the key manufacturing functions to an actual manufacturer. In comments filed with CMS last year, counsel to a POI operating in California acknowledged that his client was engaged in what he euphemistically termed "competitive outsourced manufacturing."[10] Thus, like the POIs that acknowledge their distributor status, such purported manufacturer POIs add no real value to the manufacture and sale of implants other than their mark-up on the outsourced implant product.[11]

---

[8] In fact, this seems to be a marketing highlight of many POIs as a way to cut costs out of the implant process, completely ignoring the important and necessary role representatives play in assisting device implantation. *See supra* note 5.

[9] *See* Office of the Inspector General, Advisory Opinion No. 02-12 (Aug. 30, 2002); *see also* Office of the Inspector General, Advisory Opinion No. 99-12 (Nov. 23, 1999).

[10] Letter from W. Bradley Tully to CMS dated August 29, 2007 at 3.

[11] We acknowledge that designing and manufacturing truly innovative products that could benefit patients is a legitimate business for physicians to be engaged in. However, that is not the business model being pursued by the purported manufacturer POIs that are the subject of this paper. Moreover, innovation does not justify allowing physician-owners to directly profit from the implant orders they make for their own patients. All of the legitimate implant manufacturers work with physician consultants in an effort to keep developing the latest and best products and have to compete against each other based solely on the quality and cost of those products. Thus, there are ample

C. GPO POIs

Finally, some POIs have organized themselves in an attempt to take advantage of the anti-kickback "safe harbor" for GPOs.[12] Under that safe harbor, product manufacturers are permitted to pay administrative fees to GPOs acting on behalf of their hospital members. These fees are always based on the volume or value of purchases made through the GPO.

A true GPO can add value for its hospital members by aggregating the buying power of a large number of members to negotiate lower prices from a wide variety of manufacturers. Like true GPOs, POI-GPOs have an incentive to increase utilization of the products on which they receive GPO fees. However, unlike a true GPO, a POI-GPO, through its physician owners, can increase utilization of the GPO's product lines as the physicians require the hospitals where they perform their procedures to order POI implants for those procedures. Both the value of a physician-owner's investment interest and any return on investment is based on the size of the GPO fees paid by the manufacturer; thus, the more products ordered, and the more expensive those products, the more the physician earns from his ownership in the POI-GPO. There is no counterbalancing incentive to acquire lower cost items because the physicians ordering the products are not the purchasers – they have no money at stake in the transaction.

In addition, the GPO marketplace for medical device purchasing is dominated by a small number of large, national companies that, by virtue of their large membership, have substantial buying power.[13] While at least one government study has questioned whether GPOs of any size reliably give access to the best discounts for their members,[14] there is little if any reason to believe that a relatively new POI-GPO would be able to generate the volume of membership that would give it bargaining leverage on price equal to that of the current GPO players. In other words, one could reasonably expect that the prices that a POI-GPO would be able to negotiate would be higher, or at least not lower, than a hospital could receive through the current GPO market leaders. And of course, even if a POI-GPO did manage to deliver lower pricing to a hospital member, that would not change the fact that the product selection would be driven inappropriately by the physicians' economic interests.

---

opportunities for physicians with truly innovative ideas to employ their talents in arrangements that would reward real innovation, including through ownership in an implant company, without also allowing physicians to profit from their own self-referred sales.

[12] 42 C.F.R. § 1001.952(j); 42 U.S.C. § 1320a-7b(b). The GPO safe harbor protects only fees paid to an entity "acting as a purchasing agent" on behalf of a hospital principal. Although it is fundamental agency law that the agent's duty to its principal prohibits it from converting the principal's business opportunities to the agent's benefit, it is evident that such conversion is exactly what physician-owned GPOs are intended to achieve. As such, the physician-owned GPO does not qualify as legitimately "acting as a purchasing agent" and, thus, the safe harbor does not protect vendor fees to POI-GPOs. Moreover, the GPO safe harbor protects only fees paid to the GPO, not the financial return the physician receives from owning the GPO.

[13] The Government Accountability Office has estimated that the seven largest GPOs account for over 85 percent of all hospital purchases through GPOs. *See* GAO Report No. 03-998T, *Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products* (July 16, 2003).

[14] GAO Report No. 02-690T, *Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices* (April 30, 2002).

2. How POIs Violate the Federal Anti-Kickback and Stark Laws

The descriptions above make clear that while POIs assume a number of different guises, they all share the same essential flaw: they provide their physician-owners with a strong economic incentive to leverage their hospital admissions into implant purchases for their own patients based on the physicians' financial interests, rather than the best interests of patients. As set forth more fully below, this flaw causes POIs to implicate, and most likely violate, both the federal anti-kickback statute and the Stark physician self-referral law.

A. POIs Exist to Direct Prohibited Remuneration to Physicians in Violation of the Anti-Kickback Statute

The federal anti-kickback statute prohibits, among other things, giving or receiving any financial benefit or "remuneration" in exchange for, or to induce, the referral of any patients for, or the purchase, lease, order or recommendation of, any item or service for which payment may be made under Medicare or other federal health care programs.[15] Penalties for violation of the statute include substantial criminal fines, imprisonment, exclusion from participation in federal health care programs, and/or civil monetary penalties.[16] Courts and administrative bodies interpreting the law have stated the broad rule that the statute is violated if even "one purpose" – as opposed to a sole or primary purpose – of a payment arrangement is to induce referrals for services or purchases of items reimbursable under a federal health care program.[17] Of particular relevance here, where improper intent was present, courts have found unlawful remuneration in the giving of an opportunity to earn a profit[18] and in earning a return on an investment.[19]

Thus, the anti-kickback statute is implicated if one purpose of offering referring physicians an opportunity to invest in a POI is to induce those physicians to order implants for their patients through that POI. Likewise, hospital agreements to buy, and manufacturer agreements to sell, products through a POI could violate the anti-kickback statute if one purpose was for the physicians' return on investment in the POI to act as an inducement to perform procedures at a particular hospital, or to order a particular manufacturer's products. The only real question is one of intent.

---

[15] 42 U.S.C. § 1320a-7b(b).

[16] 42 U.S.C. § 1320a-7 (exclusion from Federal Health Care Programs); § 1320a-7a (civil monetary penalties of up to $50,000 per act plus three times the remuneration); § 1320a-7b(b) (imprisonment of up to five years or criminal fines of $25,000 or both); 18 U.S.C. § 3571 (augmenting penalties: $250,000 per violation for individuals and $500,000 per violation for entities).

[17] *See, e.g., United States* v. *Greber*, 760 F.2d 68, 72 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

[18] *See Bay State Ambulance and Hospital Rental Services, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989) ("[g]iving a person an opportunity to earn money may well be an inducement to that person to channel Medicare payments toward a particular recipient").

[19] *See Hanlester Network* v. *Shalala*, 51 F.3d 1390, 1401 (9th Cir. 1995) (affirming the finding of the Department of Health and Human Services Departmental Appeals Board that the opportunity for physician-investors to earn money from their investment in a laboratory partnership was remuneration for purposes of the anti-kickback statute).

While the statute requires proof of the parties' state of mind in any individual transaction, there would seem to be ample evidence in the structure and marketing of the POI business models from which an intent to induce referrals and product selection could be easily inferred. In particular, we are confident a government inquiry would confirm that the POIs of which we are aware contain most of the following "questionable features" identified by the OIG in its 1989 *Special Fraud Alert* on fraudulent physician joint ventures,[20] all of which are indicative of an unlawful intent to induce federal program business:

- Choice of Investors. Investment interests are offered exclusively or primarily to surgeons without any particular purchasing, distribution, or management expertise, but who are in a position to order implants for their own patients through the POI. Those interests typically may not be transferred without the consent of the POI, which works to ensure that ownership remains in the hands of referring physicians. If other investors are permitted, the arrangement is structured so that a sufficient number of referring physician-investors will be retained to maintain the business' profitability. As the OIG noted in the *Special Fraud Alert*, where physicians are specifically targeted as investors, a joint venture may be suspect as "intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals."

- "Shell" Entity. The POI is an entity that does not own any assets, have any employees, or perform any actual business functions itself. In many cases, the organizer of the POI provides comprehensive management services for the venture, including contract negotiation services. As a result, the organizer provides the operating capacity for the joint venture entity, making that entity little more than a shell that has no need for investment capital. The need for investment capital also is minimized by the fact that POIs typically do not acquire nor keep any product inventory on hand.

- Financing and Profit Distribution. Because the physician investment vehicle is a shell that has little need for investment capital, the amount of capital invested by the physician-investors may be disproportionately small (as little as $5,000 per physician in some cases) and the returns on investment disproportionately large when compared to a typical investment in a new business enterprise, and the amount of return may be extraordinary based on the level of risk involved. In some cases, a single organizer forms a series of local POIs that it manages as separate entities, which appears to be a deliberate strategy to create a more direct relationship between the volume of business generated by the physician-owners and the return on their investment.

- Captive Referral Base. The POI predominantly serves the physician-investors' own patients and does business predominantly with the hospitals where the physician-investors refer their patients. The POI typically does not intend to expand the business to serve new customers (i.e., additional hospitals or other providers where the physician-

[20] The 1989 Special Fraud Alert is available on the OIG's website at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

investors do not refer patients) and, therefore, makes no or few *bona fide* efforts to do so except by recruiting new physician-investors who also would self-refer.

- Little or no *Bona Fide* Business Risk. The physician-investors' primary contribution to the POI is referrals; they make little financial or other investment in the business, or any financial investment is not significant relative to their income or net worth. Since the physician-investors determine the amount of business that is done with the POI through their own captive patient referrals, and since hospitals and product manufacturers who want the business of the physician-investors will have little choice but to deal with their POI, there is little doubt that the business will succeed as long as a sufficient number of referring physician-investors is recruited and sustained.

- Scope of Services Provided by the POI. To the extent it purports to perform any real services at all, the POI offers distributor or GPO services that are already offered by competitors that are not owned by referring physician-investors, and that are at least as well and often better qualified – by reason of greater experience or negotiating leverage brought about by size – to furnish those services more cost-effectively than the POI. The POI thus serves no apparent function other than to give its physician owners the opportunity to profit from the orders they make through the product supply chain, and that would take place anyway without the imposition of the POI.

In sum, it is evident that physicians are sought as investors in POIs *not* for their capital *nor* for their business acumen, but because of their trusted authority over choice of product and choice of facility and, most importantly, their unique ability to bring those two decisions together through a POI. Moreover, the fact that POIs are not credible competitors in the implant marketplace calls into question why anyone would contract with them *but for* their ability to return a portion of sales revenue to the referring physician-investors who have the ability control implant ordering decisions at their hospital. Under these circumstances, it is difficult to take seriously any argument that "one purpose" of the remuneration a physician gains through a POI is not to induce the physician to leverage his hospital admissions to make the hospital order products through the POI. In other words, even without in-depth investigation, the *prima facie* case for an anti-kickback violation is a compelling one.

B. POIs Do Not Qualify for Safe Harbor Protection

While a facial violation of the anti-kickback statute can, in some cases, be avoided by structuring an arrangement in accordance with one of the regulatory safe harbors, [21] such protection is not available in the case of physician ownership of POIs. Notably, the applicable safe harbor[22] for

[21] *See* 42 C.F.R. § 1001.952.

[22] Although the safe harbor for GPOs arguably could protect administrative fees from a manufacturer to a POI-GPO, and the sale of the products themselves possibly could be protected as a discount, neither of these safe harbors would protect the physician's return on investment from his ownership in the POI from being found to be unlawful remuneration if the improper intent to give the physician a profit in exchange for his business were an underlying purpose of the arrangement. *See* 42 C.F.R. §§ 1001.952(j), (d). *See* 56 Fed. Reg. 35,952, 35957 (July 29, 1991) (in the case of "a 'multi-purpose' payment practice . . .[c]ompliance with one [safe harbor] . . . would not insulate the

investment interests in non-publicly traded entities contains an important condition that limits safe harbor protection to entities that derive no more than 40 percent of their gross revenues from referrals or business otherwise generated by investors, such as physicians.[23] We do not believe that any of the POIs of which we are aware can meet this standard. This is not a mere technicality. As the OIG noted in its October 2006 letter regarding POIs, "the fact that a substantial portion of a venture's gross revenues is derived from participant-driven referrals is a potential indicator of a problematic joint venture."[24] In particular, in adopting the safe harbor regulations, the OIG observed that:

> [E]ntities protected under this safe harbor provision should not exist by relying on their business coming from referrals from investing physicians. In our experience, a large number of joint ventures are formed with the intent to encourage investors to refer patients to the joint venture. In many cases, the referrals from investing physicians dominate the joint venture's business so that it does not have to compete for outside business and that it cannot survive without such referrals from its investing physicians. *At that point, the business purpose of the joint venture becomes suspect.*[25]

In addition, we suspect an investigation would reveal that many POIs do not meet a number of the other investment interest safe harbor conditions,[26] including requirements that (1) no more than 40 percent of the interests in each class may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (which, notably, includes interests held by a POI organizer who provides management services to the joint venture), (2) the terms on which interests are offered to referring physicians who are passive investors (i.e., not involved in day-to-day management of the entity) must be no different from the terms offered to other passive investors, (3) the terms on which interests are offered to referring physicians must not be related to the previous or expected volume of referrals from, or business generated by, the physician for the entity, and (4) there is no requirement that a physician who is a passive investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor, which may be violated by provisions requiring physicians to divest their interest if they retire or are no longer actively engaged in the practice of medicine in the markets served by the POI.

Although failure to qualify for a safe harbor does not necessarily mean that the anti-kickback statute has been violated, arrangements outside of the safe harbors are subject to scrutiny and challenge.[27] This is especially true in the case of POIs because, as we explain below, they

---

entire payment practice from criminal prosecution . . . where *another purpose* of the payment practice is implemented in a manner which violates the statute") (emphasis added).

[23] *Id.* § 1001.952(a)(2)(v).

[24] *See supra* note 1.

[25] 56 Fed. Reg. 35,970 (emphasis added).

[26] 42 C.F.R. § 1001.952(a)(2).

[27] 54 Fed. Reg. 3088, 3089 (1989); 56 Fed. Reg. 35,952, 35,954 (July 29, 1991).

present such significant risks of patient and program abuse.

C. POIs Create Financial Relationships Prohibited by the Stark Law

POI arrangements also create financial relationships between their physician-owners and their hospital customers that implicate the federal physician self-referral law, commonly known as the "Stark" law.[28] More specifically, the Stark law prohibits physicians, subject to limited exceptions, from making referrals to an entity with which they have a financial relationship for certain designated health services (DHS) – including inpatient and outpatient hospital services – reimbursable by the Medicare program.[29] Notably, the Stark law imposes conflict of interest restrictions that apply whenever a direct *or indirect* financial relationship exists between a hospital and a physician, without regard to any intent to induce referrals. Thus, if there is a financial relationship, the Stark law prohibits the physician from referring *any* Medicare patients to the hospital for *any* services, unless an exception applies. And unlike the anti-kickback law safe harbors, full compliance with a Stark exception is required to permit referrals that otherwise would be prohibited by the Stark law.

In the case of POI arrangements, CMS has recognized that in many cases "an unbroken chain of financial relationships will connect the physician owner of a [POI] to a DHS entity [i.e., a hospital] to which the physician makes referrals," thereby creating an indirect financial relationship under the Stark law.[30] Accordingly, any Medicare referrals to a POI hospital-customer from a physician-owner are prohibited unless the arrangement meets the requirements of the relevant Stark law exception for indirect compensation arrangements.[31] Among other things, that exception requires that the compensation paid within the chain of financial relationships must not vary with or otherwise reflect the volume or value of referrals generated by the referring physician, which would seem difficult to meet where the implants purchased through a POI are most often directly related to the number of implant surgery cases referred to the purchasing hospital by the physician-owners of the POI. Indeed, CMS has also recognized that "[i]n many instances, the [financial] arrangement would not satisfy the requirements of the exception for indirect compensation arrangements . . . and would, therefore, run afoul of the physician self-referral statute."[32]

Distinct from the anti-kickback statute, the Stark law provides an additional enforcement mechanism when examining the abuses presented by POI arrangements. Since the Stark law does not require any evidence of specific intent to induce referrals, it may provide a more direct and simplified way to protect patients and the Medicare program from self-referral abuses

[28] 42 U.S.C. § 1395nn.

[29] 42 C.F.R. § 411.353(a).

[30] 73 Fed. Reg. 23528, 23695 (April 30, 2008).

[31] 42 C.F.R. § 411.357(p).

[32] 73 Fed. Reg. 23695.

inherent in POI arrangements. Because compliance with the Stark law is a condition of Medicare payment, Stark law violations also may create liability under the False Claims Act.[33]

On the other hand, to date CMS has declined to state categorically that POIs violate the Stark law, and so the organizers and physician-investors in these ventures apparently continue to feel comfortable operating in a climate of "unsettled law." In this environment, it may be that the less technical anti-kickback statute is the preferred enforcement mechanism against the inherent abuses in the POI business model. It is those abuses that we turn to next.

3. Significant Patient and Program Abuses are Inherent in the POI Business Model

Where, as here, all the elements of a legal violation are present and no regulatory safe harbor protection is available, the exercise of prosecutorial discretion to pursue an investigation usually is driven by an assessment of the potential for program or patient abuse. In the case of POIs, those risks are inherent, significant, and ongoing – all of which points to an urgent need for further government inquiry.

A. POIs Present Medical Ethics Concerns

To begin with, physician-investment in a POI through which the physician orders implants for his or her own patients raises serious ethical concerns. The Council on Ethical and Judicial Affairs of the American Medical Association (AMA) has cautioned against a physician prescribing drugs, devices, or appliances if that physician is otherwise influenced in the prescription by a direct or indirect financial relationship with the supplier.[34] Physician-investors in POIs no doubt will contend that their choices are not influenced by the financial interest; yet that assertion must be weighed against the powerful economic incentives that are created when a hospital agrees to acquire implants from a physician's POI.

Further, in a separate opinion, the AMA Council issued guidance about physicians selling products in their offices, stating that physicians should severely restrict their sale of items directly to patients because this "presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own."[35] The AMA Council's concern over sales of products in physician offices correlates precisely to the concerns with physicians deciding which implant to use on their patients: not only is there potential that the financial incentive can cloud the physician's judgment, but there is also a disturbing appearance of overreaching as relates to patients.

---

[33] *See United States* v. *Rogan*, 459 F.Supp. 2d 692, 717 (N.D. Ill. 2006) (*citing United States ex rel. Schmidt* v. *Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004)).

[34] American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.06, *Prescribing and Dispensing Drugs and Devices*.

[35] American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.063, *Sale of Health-Related Products from Physicians' Offices*.

Thus, established medical ethics principles present a good starting point for analyzing POI investments by physicians.

B. POIs Are Likely to Corrupt Medical Decision Making

The conflicts of interest inherent to the POI business model create what would seem to be almost irresistible incentives to direct hospital admissions for implants exclusively to those facilities that agree to provide the physician-owner with an economic return by acquiring implants through his or her POI. Thus, the physician's mind is likely to be closed to, or at least prejudiced against, implants from other sources and hospitals that refuse to deal with the physician's POI. The likely result is that inappropriate implant choices will be made. Moreover, we have reason to believe that further investigation will reveal that the physician-owners of POIs and their agents exert pressure on hospitals to purchase implants through their POIs through subtle – or sometimes not so subtle – threats that if they do not, the physicians will take their patients and their implant surgery cases elsewhere.

C. POIs Are Likely to Lead to Higher Implant Costs

Not only will product choice inevitably be affected, but there is every reason to assume the end result of implant procedure choices being made through POIs will be higher costs for such procedures. Since physicians can control the venue for their implant procedures, they are in a position to insist that hospitals buy through their POIs.[36] And since physicians have this control over hospital implant purchasing, hospitals will have little ability to negotiate for lower implant prices, as they will have lost the leverage to turn to other implant suppliers. Similarly, once physician-owners convince a hospital to purchase from their POI, the POI will have the power to raise prices almost at will, since the hospital that declines a price increase is likely to see the POI-owner physicians take their procedures to another hospital. Again, government inquiry into the realities of this dynamic would seem to be vitally important to the integrity of the Medicare program.

The same conflicts of interest may even lead to overutilization, with physician-investors ordering procedures of questionable medical value in order to utilize more POI products and increase the return on their investment.

D. POIs Are Anti-Competitive

Because of the physician's ability to control implant purchasing by the hospital in favor of his or her POI, POIs distort competition in the implant and implant procedure market. Hospitals must acquire the implants their referring physicians require or the physicians will perform their procedures at other hospitals that do; thus, POIs control both the supply and the demand for their products. In contrast, legitimate device manufacturers do not have the advantage of controlling the demand for their products. Rather, they must compete against each other based on the cost

[36] In discussing the buying power forces in the orthopedic industry, an analyst report characterizes orthopedic-market purchasing as a market where "healthcare facilities [are] buyers, assuming that their buying choices experience strong pull-through from the clinicians who use these products." Data Monitor, *Orthopedics in the United States*, Industry Profile at 12 (July 2007).

and quality of their implantable products, their responsiveness to customer orders and service needs, the strength of their warranties, and the like. Similarly, competitors to those hospitals that have agreed to deal with a POI are at an impossible disadvantage; unless they offer the referring physician the same economic benefit as the POI, superior service, location, and facilities often will not be sufficient to attract the physician's procedures. Not only is it unfair to these legitimate competitors for POIs to have this advantage, the competitive unfairness is likely to lead to all the evils traditionally associated with monopolies: higher costs, poorer product quality, and less innovation.

E. POIs Can Lead to Substandard Patient Care

Finally, though perhaps most importantly, POIs present risks to patient care. We have already established that the conflict of interest that inheres in POIs is likely to have a profound effect on procedure venue, physician product choice, and implant utilization. Such incentives create the very real possibility that the best interests of patients will be sacrificed in the pursuit of profits for the POIs and their physician-owners. In particular, our medical device clients have observed that many of the implants they see being sold through POI arrangements do not have the documented history of clinical success commonly associated with the devices developed by more established manufacturers. As a result, there is a very real concern that financial incentives are causing the physician-owners of POIs to use inferior products and jeopardize the health of their patients.

4. The Claimed Benefits of POIs and Alleged Safeguards Against Abuse are Illusory

We have encountered several claimed benefits of POIs and alleged safeguards against patient and program abuse that POI advocates contend are built into their arrangements. As we explain below, however, these purported benefits and safeguards seem unlikely to exist in most POIs and, in any case, do not appear to provide adequate protection against the serious abuses inherent to the POI business model. Certainly, given the very real potential for abuse, the asserted benefits and safeguards merit investigation and close scrutiny to determine whether they, in fact, have any basis in reality, or whether they are instead just the window-dressing of creative lawyers.

A. Asserted Benefit: POI sales are aimed to reduce hospital implant costs in the short term and, in the long term, costs to the Medicare program.

As discussed above, there is no evidence or logic behind the claim that POIs will lead to lower implant costs. All the incentives run in the other direction – adding a middleman to the supply chain and encouraging POI investors to order more, and more expensive products and perform more procedures.

A number of POI advocates claim their POIs promote the same cost-saving benefits seen in a number of "gainsharing" programs approved in recent years through OIG advisory opinions. The "gainsharing" programs approved by the OIG have all involved proposals to share with physicians demonstrated cost savings to which the physicians have been shown to contribute by reducing expenses including, in part, by ordering only standardized products. In contrast, physician investment in POIs involve sharing with physicians not *cost* savings, but the *profits*

earned by the POI based on products ordered by the referring physician investors for their own patients. These profits are maximized not by generating demonstrable cost savings, but by ordering more, and more expensive products. Product "standardization" in these circumstances is not likely to result in any cost savings.

POIs also claim they can reduce costs by eliminating "unnecessary marketing expenses," in particular by eliminating the role of "expensive commissioned sales representatives." Such claims ignore the well-known reality that in the implant industry, the manufacturer representative is an essential participant in the delivery of patient care. Industry representatives provide initial and ongoing training and education on the safe and effective use of products, updates on new technologies and applications, support in the proper programming of electronic devices, and in the case of many implantable devices, support in the operating room during the implant procedure. Simply eliminating that role would have adverse consequences for the quality of patient care.

Moreover, marketing costs are essential in running a business for which there is actual competition – especially when there are many choices to be made between similar products. Indeed, without advertising and marketing, there is no way to assure that a medical device will have adequate exposure to potential purchasers. Therefore, one can only conclude that – having rid itself of the "expensive commissioned sales representatives who are critical to assisting in procedures, and the marketing apparatus that would make it possible to sell products to physicians other than insiders – a POI can be successful only if its customers are the physician-investors who order their company's products for their own patients. Yet, this is the very conflict of interest that we believe makes physician ownership of POIs unlawful.

B. Asserted Benefit: Physician investment in POIs will lead to greater innovation in the implant market.

There is no reason to believe that POIs will lead to positive innovation in implant design and manufacture. To begin with, most POIs do not design or manufacturer their own devices. In the rare case of those that do, because POIs have the ability to control the demand for their products, there is no economic incentive to make better products. Rather, the most advantageous manufacturer POI for a physician-investor would be one that licenses a copycat product, thereby negating the need to spend money on product design and development.

In contrast, legitimate device manufacturers, which do not control the demand for their products, have strong competitive incentives to continually improve their products, and produce them at lower cost. All the existing evidence is that the skill and knowledge of innovative physicians is widely-sought by legitimate device manufacturers. It also is reasonable to expect that the input of physician consultants into product design and development is likely to be more objective when the physicians cannot profit from their own implant referrals. And for physicians who have truly innovative ideas that they want to pursue on their own, we do not believe they should be prohibited from owning a *bona fide* implant development and manufacturing company; rather, they simply should have to compete on the same playing field as other product manufacturers, selling their products only to customers other than themselves and their POI co-investors. Indeed, there are ample opportunities for physicians with good product ideas to develop them in businesses that are not built on the economics of leveraging patient admissions in exchange for

the opportunity to profit from orders of their own company's products for their own patients. That some POI organizers or physicians might prefer the more expeditious route of simply creating or investing in a company specifically designed to sell to its own captive physician-investor customer base, bypassing the safeguards of real competition, bespeaks a purpose of payment for referrals, not product innovation.

C. Asserted Safeguard: The ability of any one physician investor in a POI to influence decision-making and supply selection will be de minimis.

Although this assertion might be true if a particular POI were successful in becoming a sufficiently large company, it would of course not be true during the venture's start up phase, nor if it remains owned largely by a relatively small number of referring physician investors or contracts only with a small number of hospitals. However, whether it is true or not, this assertion is at best a trivial safeguard against abuse. As noted above, the economic success of POIs is based on referring physician investors ordering products for their own patients. While any one referring physician investor may be unlikely to be able to affect the POI's overall revenues by his own actions, in the aggregate *all* of the referring physician investors will clearly understand that it is their collective commitment to dealing only, or at least primarily, with hospitals and suppliers who utilize their POI that will make the business profitable, and the more such utilization there is, the more profit there will be for the physicians as a group.

D. Asserted Safeguard: The POI's supply selection will be based on an analysis of price and clinical efficacy and safety, and not on the preference or financial interest of any one physician investor.

In the POIs we have seen, the "medical directors" who make these assessments are comprised of referring physician investors, thus making the veracity of these assurances suspect. Moreover, given that most legitimate implant manufacturers so far have declined to incur the legal risks of selling through POIs, we doubt that clinical efficacy and safety are being given serious consideration in most POIs.

However, even were it the case that such analysis became the norm, this would not constitute a significant safeguard against abuse. As noted above, all of the referring physician investors will have the same financial incentives – pushing manufacturers to sell and hospitals to buy predominantly through the POI, with the attendant risks of higher prices, inappropriate effects on product choice, and unfair harm to legitimate competitors. That price and safety will be considered in negotiating product contracts adds nothing to what hospitals already do, and thus does nothing to counteract the effect of these new and powerful economic incentives.

E. Asserted Safeguard: Physician investors and hospitals will make disclosures to affected patients.

Presumably, any physician making a disclosure about a financial interest in a device would assure the patient that his or her financial interest was immaterial to the decision to perform the procedure or to the choice of implant. Most patients will not be sufficiently skeptical of their

own physician to be able to make meaningful use of such information.[37] Moreover, the implant market is not one where consumer choice even operates in a very meaningful way. Surgeons tend to use the implants that they prefer and a patient's only choice, if he or she prefers a different product, typically would be to change physicians. Unlike, for example, a disclosure by an ophthalmologist that the patient may buy eyeglasses from him or take the prescription elsewhere, physicians do not present their patients with a choice of implants, and even if they did, patients are not in a position to evaluate whether one is better than another. This so-called safeguard, in other words, is an illusion.

F. Asserted Safeguard: Referring physician investors will be required to participate in a meaningful implant identification, consideration, and quality assurance process.

This feature is not a safeguard at all, but rather a restatement of the problem: by giving referring physician investors a financial interest in the products they order for the hospitals to purchase, their decisions about choice of implant will be compromised.

G. Asserted Safeguard: The ability to purchase from a POI will be available to all hospitals, thereby minimizing the risk that referring physician investors will shift patients among hospitals in a given community.

To the contrary, POIs provide referring physician investors with a strong economic incentive to shift patients to hospitals that are willing to purchase through the POI. That any willing hospital may participate does not minimize this risk to competitors not willing to participate in the scheme. Nor does it guard against any of the other abuses noted above.

H. Asserted Safeguard: Physician investors will be required to execute an affidavit asserting they will not allow their investment in the POI to improperly affect their patient care decisions.

Even presuming that the referring physician investors in the POI would provide such undertakings with the best of intentions, such declarations do not even begin to overcome the overwhelming economic incentive that motivates physicians to invest in the first place, nor provide any safeguard against the abuses outlined above. Moreover, the POI arrangements that we are aware of do not appear to incorporate any features to track or enforce the statements in the affidavit, a failing that has traditionally concerned the OIG when supposed safeguards are intended to guard against an economic incentive. Additionally, it is simply not credible to argue that a physician will be able to array pricing options available for various implants that the hospital may have contracts to purchase. It is the fundamental conflict of interest inherent in the

[37] There is ample social science evidence that disclosure of financial conflict-of-interest is not a meaningful protection, and in fact has the perverse effect of lending credibility to the message of the discloser rather than breeding skepticism. *See, e.g.*, Diana and Lowenstein, "*A Social Science Perspective on Gifts to Physicians from Industry*," 290 JAMA 252 (2003) ("Disclosure can only be effective it those informed can rationally update their beliefs – discount the advice they receive from physicians who disclose financial conflicts of interest – in light of the disclosure. However, most patients would have little idea about, for example, how much to discount their physician's recommendation to participate in a clinical trial if they were informed that their physician would benefit financially from their participation.").

physician's investment in the POI that will, even if not consciously, drive that physician's ordering decision. That is, after all, the whole purpose of the venture – an unlawful purpose that cannot be saved through a self-serving and unverifiable affidavit.

5. Conclusion

At bottom, POIs are mostly, if not exclusively, about creating opportunities for physicians to profit from their own referrals. We are confident that the abuses inherent to the various POI business models are currently occurring in the U.S. markets for cardiac and orthopedic implants, presenting conflicts of interest that can only interfere with physician judgment about whether to perform a procedure, the best products to use, and where procedures are performed. Thus, we believe government enforcement officials should take a closer look at how these entities are impacting patient care decisions and the federal health care programs that continue to cover a significant majority of surgical implants.

Thomas N. Bulleit Jr.
Stephen J. Immelt
Ronald L. Wisor Jr.

February 3, 2009