

Physician-Owned Intermediaries in the Medical Device Industry: Fraud and Abuse Compliance Risks for Physicians, Hospitals and Manufacturers

This paper has been prepared by Hogan & Hartson to highlight the fraud and abuse compliance risks associated with the growing 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 exists to give its surgeon-investors the opportunity to profit from the sale of certain medical devices to hospitals. At present, POIs appear to be focused in the orthopedic implant (e.g., artificial hips, knees and spinal products) and cardiac implant (e.g., pacemakers and defibrillators) sectors of the device industry, where implant selection is determined by physician preference, thus giving POIs the ability to influence hospital purchasing decisions to benefit their physician owners in violation of the federal fraud and abuse laws. More specifically, the physician-investors in POIs, and the hospitals and implant manufacturers who deal with them, risk substantial liability under the federal anti-kickback statute, as well as under the Stark law and the False Claims Act, for participating in this business model.

Simply put, we do not believe that physician ownership of 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. In particular, we assert the following:

- 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.

¹ POIs also are sometimes referred to as “POCs” or physician-owned companies.

- In contrast to the hospitals who actually purchase the devices, the physician-owners of POIs have no incentive to keep costs down, so that physician ownership of POIs is likely to lead to higher costs over time. This is especially true where, as is often the case, the POI is a hospital's exclusive provider of implants, thus taking away any ability for the hospital to negotiate with other vendors for lower prices.
- Finally, POIs have an unfair effect on competition because hospitals who want a POI's physician-owners to perform procedures at their facilities, and manufacturers who want those physicians to use their products, will have no choice but to deal with the POI, even if it is more expensive to do so and even if the POI is not as well-qualified as its competitors.

Both the Office of Inspector General of the Department of Health and Human Services (“**OIG**”) and the Centers for Medicare & Medicaid Services (“**CMS**”) have expressed serious legal and program integrity concerns with POIs. In October 2006, the 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 Similarly, CMS has been critical of POIs, and has considered amending its Stark physician self-referral regulations to address them more specifically.⁴ CMS has stated that these entities “serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients,”⁵ and that in many instances such physician-owned entities “would...run afoul of the physician self-referral [Stark] statute.”⁶

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”).

⁵ Centers for Medicare and Medicaid Services, Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23527, 23694 (April 30, 2008).

⁶ 73 Fed. Reg. 23695.

Given these expressions of serious legal concern from OIG and CMS, it is only a matter of time before government authorities, acting on their own or with the assistance of private whistleblowers, bring enforcement actions against the physician-owners of POIs and the hospitals and medical device manufacturers who deal with them. Moreover, since violations of the Stark law prohibit Medicare payments for any hospital services referred by a physician with a prohibited financial relationship, and require refunds for payments received pursuant to a prohibited referral, hospitals that accept referrals from physicians whom they know or should know are investors in a POI are subject to penalties and repayment obligations that increase with each new referral from a POI physician.

To better explain to stakeholders the inherent unlawfulness and legal liabilities associated with the POI business model, we set forth below (1) a more detailed description of the most common types of POIs, (2) the legal case for how these entities implicate, and most likely violate, the federal anti-kickback statute and the Stark physician self-referral law, as well as provide a ready vehicle for whistleblower enforcement under the federal False Claims Act, and (3) the patient and program abuses inherent to the POI business model.

1. Types of POIs

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."⁷

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. 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.⁸ 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

⁷ 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).

⁸ 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.

to the hospital in response to a specific order from a physician who plans to implant the product into his or her patient.

In practical terms, this means that many distributor POIs likely do *not* actually acquire and take physical possession of the devices they sell. In fact, a recent trend has seen the growth of POIs that make no pretense of being a product distributor, but instead simply receive commissions from manufacturers for arranging implant purchases by the hospitals where the POI's physician owners perform surgery. As a result, 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, who coordinate ordering and distribution, supply instrumentation for use in procedures and, in many cases, assist physicians during procedures in the operating room.⁹ In fact, eliminating allied health professionals 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 they play in assisting safe device implantation.

Therefore, 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,¹⁰ including generating business for themselves via referrals for procedures involving POI-provided products.

⁹ See 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).

¹⁰ See 56 Fed. Reg. 35799, 35974 (July 29, 1991) (stating that marketing and advertising activities may warrant prosecution if “the individual or entity involved in these promotions is . . . involved in the delivery of health care [and therefore] in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients.”); see also OIG Advisory Opinion No. 02-12 (Aug. 30, 2002) (stating that marketing by health care providers “is subject to closer [anti-kickback] scrutiny, since health care practitioners are in a position of trust and may exert undue influence when recommending” products); OIG Advisory Opinion No. 99-12 (Nov. 23, 1999) (“[m]arketing by physicians . . . is closely scrutinized under the anti-kickback statute . . . [physicians] are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services, especially when marketing to their patients”).

In sum, distributor POIs provide no real value other than adding costs to the supply chain. 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, supply chain 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 claim 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.”¹¹ Thus, like the POIs that claim to be distributors, 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.¹²

C. GPO POIs

Finally, some POIs have organized themselves in an attempt to take advantage of the anti-kickback “safe harbor” for GPOs.¹³ 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

¹¹ Letter from W. Bradley Tully to CMS dated August 29, 2007 at 3.

¹² 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 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.

¹³ 42 C.F.R. § 1001.952(j); 42 U.S.C. § 1320a-7b(b). The GPO safe harbor only protects 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. That being the case, a physician-owned GPO may not qualify as legitimately “acting as a purchasing agent” and, thus, the safe harbor may not protect vendor fees to POI-GPOs. Moreover, the GPO safe harbor only protects the fees paid to the GPO, not the financial return the physician receives from owning the GPO.

true GPOs, POI-GPOs have an incentive to increase utilization of the products on which they receive GPO fees. Unlike a true GPO, however, a POI-GPO can, through its physician owners, increase utilization of the GPO's product lines as the physicians require the hospitals where they perform procedures to order implants for those procedures through the POI. The return on a physician-owner's investment interest is based on the size of the GPO fees paid by the manufacturers; 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.¹⁴ While at least one government study has questioned whether GPOs of any size reliably give access to the best discounts for their members,¹⁵ there is no 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. Rather, 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.

2. How POIs Violate the Federal Fraud and Abuse 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, the federal anti-kickback statute, the Stark physician self-referral law and the False Claims Act.

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

The federal anti-kickback statute prohibits 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.¹⁶ Penalties for violation of the statute include

¹⁴ 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).

¹⁵ GAO Report No. 02-690T, *Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices* (April 30, 2002).

¹⁶ 42 U.S.C. § 1320a-7b(b).

substantial criminal fines, imprisonment, civil money penalties and exclusion from participation in federal health care programs.¹⁷ 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.¹⁸ Of particular relevance here, where improper intent was present, courts have found unlawful remuneration in the giving of an opportunity to earn a profit¹⁹ and in earning a return on an investment.²⁰

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.

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,²¹ 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,

¹⁷ 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).

¹⁸ See, e.g., *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985).

¹⁹ 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”).

²⁰ 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).

²¹ The 1989 Special Fraud Alert is available on the OIG’s website at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

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 often 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-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,²² such protection is not available in the case of physician ownership of POIs. Notably, the applicable safe harbor²³ for 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.²⁴ 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.”²⁵ 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

²² See 42 C.F.R. § 1001.952.

²³ 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 entire payment practice from criminal prosecution . . . where *another purpose* of the payment practice is implemented in a manner which violates the statute”) (emphasis added).

²⁴ *Id.* § 1001.952(a)(2)(v).

²⁵ See *supra* note 2.

investing physicians. *At that point, the business purpose of the joint venture becomes suspect.*²⁶

In addition, we suspect an investigation would reveal that many POIs do not meet a number of the other investment interest safe harbor conditions,²⁷ 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.

There also is no safe harbor protection for those POIs that simply receive a sales commission from manufacturers. Indeed, every court to have considered the question has held a commission on the sale of a health care product to violate the anti-kickback statute.²⁸ While these cases generally have been civil contract avoidance disputes, rather than enforcement actions, they have recognized that the purpose of a commission is to induce the recipient to sell the product.²⁹ Where the commission is not to a seller, but to the person who actually *orders* the product, not only is the potential for abuse obviously much greater, the inference of improper intent becomes unavoidable. And while the OIG does not regard commissions as *per se* violations of the anti-kickback statute, it has established a framework for when a commission is sufficiently abusive to warrant prosecution. Inarguably, the most important abuse is “the use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients.”³⁰

²⁶ 56 Fed. Reg. 35,970 (emphasis added).

²⁷ 42 C.F.R. § 1001.952(a)(2).

²⁸ See, e.g., *Nursing Home Consultants, Inc. v. Quantum Health Serv., Inc.*, 926 F. Supp. 835, 844 (E.D. Ark. 1996) (consultant’s compensation was “directly pegged to the number of sales generated”), *aff’d per curiam* 112 F.3d 513 (8th Cir. 1997); *Medical Dev. Network, Inc. v. Professional Respiratory Care/Home Med. Equip. Serv., Inc.*, 673 So.2d 565, 567 (Fla. Dist. Ct. App. 1996) (arrangement by which consultant is paid a percentage of the sales it generates violates the anti-kickback statute).

²⁹ *Nursing Home Consultants, Inc.* at 843 (stating that the sales commission arrangement was paid to plaintiff “for referring persons who needed Medicare-covered supplies . . . and this type of relationship falls squarely within the transactions prohibited by [the anti-kickback statute]”).

³⁰ See *supra* note 10.

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 by government enforcement officials.³¹ This is especially true in the case of POIs because, as we explain below, they 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.³² 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.³³ 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.³⁴ 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.³⁵ 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.”³⁶

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

³² 42 U.S.C. § 1395nn.

³³ 42 C.F.R. § 411.353(a).

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

³⁵ 42 C.F.R. § 411.357(p).

³⁶ 73 Fed. Reg. 23695.

Violations of the Stark law are subject to substantial civil monetary penalties for submitting claims for a service referred by a physician with a prohibited relationship. In addition, hospitals are required to refund to Medicare any amounts so-paid, subject to additional penalties if they do not.³⁷ Thus, if a hospital is accepting referrals from a physician with knowledge that the physician is receiving unlawful remuneration through a POI, the hospital is subject to penalties if it submits claims and more penalties if it does not do a review and refund payments already received.

D. POIs are Subject to Enforcement Under the False Claims Act

Violations of both the anti-kickback statute and the Stark law also create the potential for liability under the federal False Claims Act (“FCA”).³⁸ The FCA provides for treble damages and civil penalties between \$5,500 and \$11,000 per violation for submitting, or causing the submission of, false or fraudulent claims to the federal government or to its contractors.³⁹ Private whistleblowers are empowered under the FCA to bring actions for violations in the name of the federal government, and are entitled to share in the government’s recovery an amount up to 30 percent of all damages received in an action, plus attorney fees and other costs.⁴⁰ Thus, in addition to the potential for direct enforcement by government officials, POIs place physicians, hospitals and implant manufacturers at risk for a whistleblower lawsuit brought by disgruntled employees or competitors.

Courts have held that violations of the anti-kickback statute and the Stark law are actionable under the FCA.⁴¹ Hospitals submit claims to Medicare for services furnished pursuant to the physician’s referral, the physician causes those claims to be submitted by virtue of performing the procedure at the hospital and, if the manufacturer knows or should know of the physician’s commission, it also could be said to have caused the inappropriate claims to be submitted.

Further, apart from violations of the anti-kickback or Stark laws, where a physician performs a procedure of questionable medical necessity, the FCA is implicated notwithstanding any allegations of other statutory or regulatory violations.⁴² For example, we have heard disturbing reports of spinal surgeons performing substantially increased numbers of revision surgeries to replace existing implants *after* their investment in a POI. Because of the obvious financial incentive to overutilize with any POI arrangement, hospitals that allow a POI physician to perform procedures of questionable medical necessity run the risk that they will be viewed as

³⁷ 42 U.S.C. §§ 1395nn(g)(2) and (g)(3).

³⁸ 31 U.S.C. § 3729 *et. seq.*

³⁹ *Id.* § 3729(a).

⁴⁰ *Id.* § 3730.

⁴¹ See, e.g., *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)).

⁴² See 42 U.S.C. § 1396y(a)(1)(stating that “no payment may be made under part A or part B for . . . items and services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury”).

acting with “reckless disregard” or “deliberate ignorance” of unnecessary procedures being performed and billed.⁴³

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 government’s decision to pursue an investigation or prosecution is driven by an assessment of the potential for program or patient abuse. In the case of POIs, those risks are obvious and substantial, which makes government enforcement actions seemingly inevitable.

A. POIs Create Ethical Conflicts of Interest That Corrupt Medical Decision Making

The conflicts of interest inherent to the POI business model create seemingly irresistible incentives for physicians to direct hospital admissions for implants exclusively to those facilities that acquire implants through their POIs. Thus, a 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 his POI. The result is that physicians are incentivized to put their own economic well-being ahead of patient interest, creating an ethical conflict of interest for the physician.

Indeed, the Council on Ethical and Judicial Affairs of the American Medical Association (“AMA”) has cautioned against a physician prescribing drugs or devices if the physician is influenced by a direct or indirect financial relationship with the supplier.⁴⁴ Further, in a separate ethical 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.”⁴⁵ 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.

B. POIs Are Anti-Competitive

Because physicians have the ability to control hospital implant purchases favor of their POIs, 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

⁴³ 31 U.S.C. § 3729(b)(1)(A)(ii) – (iii)(a “knowing” violation of the FCA includes “deliberate ignorance” or “reckless disregard” of the truth or falsity of information).

⁴⁴ American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.06, *Prescribing and Dispensing Drugs and Devices*.

⁴⁵ American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.063, *Sale of Health-Related Products from Physicians’ Offices*.

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 and quality of their implants, 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 quality and less innovation.

C. POIs Are Likely to Lead to Higher Implant Costs, Lower Quality Care or Both

The ethical conflict of interest and unfair competition are reason enough for enforcement officials to challenge the POI business model, even if the implants obtained were to cost less. This risk becomes almost inevitable when coupled with the dilemma that furnishing implants through a POI must, in the end, lead to increased costs, lower quality, or both.

Indeed, there is an obvious flaw in any claim that POIs can deliver the same quality implant services at lower cost. In real competition based on price, it would be ludicrous to suggest that the manufacturer itself, selling directly, could not offer a lower price than a middleman distributor with its extra costs. In response to this observation, POI proponents cite a recent poster abstract from the January 2009 annual meeting of American Academy of Orthopedic Surgeons ("AAOS") to support the claim that POIs are capable of producing significant cost savings.⁴⁶ But a closer look reveals a faulty and misleading analysis, presented *not* by independent experts but by the POI physicians themselves. Specifically, the abstract purports to compare the hospital's pre-existing "average contract price" from implant manufacturers with the lower price that the physician-owned distributor offered. However, there is no suggestion that the prior vendors or other manufacturers were offered the opportunity to bid against the POI. If real competition had been allowed to take place, other manufacturers surely would have been able to meet any price offered by the POI distributor, since the manufacturers would not have the additional expense of the distributor's profit distributions to physicians to cover.

The reality is that because physicians can control the venue for their implant procedures, they are in a unique position to insist that hospitals buy through their POIs.⁴⁷ In fact, POIs

⁴⁶ Steinmann, et. al., *Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model*.

⁴⁷ 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).

commonly insist on being a hospital's *exclusive* provider of orthopedic or cardiac implants. By ceding control over hospital implant purchasing to POIs, hospitals will, over the long run, have little ability to negotiate for lower implant prices, as they will have lost the leverage to turn to other implant suppliers.

In the end, the implant prices offered by POIs will end up being higher because of the need to give physicians a profit margin on the product. Alternatively – or perhaps at the same time – the quality of care will be lower as qualified allied health professionals are eliminated to subsidize profit distributions to physicians and the choice of implants becomes restricted to those offered by often less-established companies willing to sell through POIs despite the legal and ethical concerns.

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.

4. Conclusion

At bottom, POIs are really about creating opportunities for physicians to profit from their own referrals, a proposition antithetical to the fraud and abuse laws. The abuses inherent to the various POI business models are currently occurring in the markets for orthopedic and implants, presenting conflicts of interest that interfere with physician judgment about whether to perform a procedure, the best products to use and where procedures are performed. These conflicts of interest not only raise significant health and safety risks for patients, but also present significant legal risks for physicians, hospitals and implant manufacturers of being prosecuted or penalized for violating the fraud and abuse laws. Given the confluence of legal problems and ethical concerns, the question is not whether POIs will come under government scrutiny, but when.

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