

ANTI-FRAUD CONCERNS FOR PHYSICIAN-OWNED DISTRIBUTORS
FOR MEDICAL DEVICE PRODUCTS: WHAT'S NEW IS OLD. WE
WON'T BE FOOLED AGAIN.

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Executive Summary

The shadowy momentum for physician-owned distributorships (“PODs”) models to advance health reform goals of healthcare cost-savings does not disguise that its predominate purpose is to achieve an increase in physician income from the sale of medical products from the physician’s own business for use in his pre-determined hospital surgeries. The business model is a vexing artifice that contradicts long standing and effective legal safeguards that protect patients and the public interest from physician conflict of interest in medical decision-making. Like all artifices, the POD model is shrouded in misleading debate by proponents of the model that purport to have the support of legal and medical experts. The expert bench, however, is thin in support of PODs and does not credibly match the extraordinary legal and ethical precedents that disfavor PODs.

Physician-owned or investor entities, moreover, have a sad legal trajectory that can be fairly predicted from over 40 years of anti-fraud legislating and prosecuting the evils of such arrangements. When physicians “take a piece of the action” from their patient referrals or related medical decision making activities, their professional effort is tainted, patients are potentially harmed and the public interest is undermined. And, yes, procedure utilization goes up...alot. Then, investigations eventually show that procedures tainted by physician conflict of interest were substantially medically unnecessary. Yes, we have been here before but we won’t be fooled again.¹ PODs are not a legally credible business model to advance healthcare cost-savings or any other legitimate public health goal. PODs cannot be safely formed consistent with fraud and abuse laws such as the federal anti-kickback statute and the physician self-referral ban (known as Stark) or with government and industry compliance best practices.

Private sector watchdogs, government regulators and enforcers, and the U.S. Senate Finance Committee have all justifiably raised compelling legal and policy concerns regarding the POD business model. Despite these concerns, POD models continue to grow. It will take focused government action to protect patients and safeguard important public health prerogatives. Public health advocates may reasonably posit that Physician ownership of health care entities has proved too great a risk to the public interest and should be have been legislatively banned or regulated to remove or diminish conflict of interest.

Government and other stakeholders such as hospitals and health systems are actively assessing the tremendous legal risk of PODs. Several community and national hospital chains and health systems have adopted policies and procedures that either ban or place significant restrictions on doing business with physician owned entities and other vendors who have a financial relationship with the hospital’s physicians. In light of the many hesitations and concerns from industry stakeholders, as well as the risks and costs associated with PODs identified through historical empirical evidence, the federal government, including the Office of Inspector General (“OIG”) and the Department of Justice (“DOJ”), has taken the position that

PODs are, at best, questionable business ventures and cannot comply with existing fraud and abuse laws.

This review focuses on the federal fraud and abuse, conflict of interest and medical ethics concerns associated with physician-owned distributor entities (hereinafter PODs) in the medical device products industry and provides a compelling rationale supporting the the OIG's recent fraud and abuse guidance and action on the anti-kickback implications of these proliferating arrangements.

I. Physician-Owned Distributor Entities in the Medical Device Industry: A Pandora's Box.

Physician owned or invested entities are controversial and have a long history of proven overutilization, quality of care and improper payment concerns. Objective empirical evidence of similar arrangement scenarios to PODs reveals a predictable pattern of higher utilization and medically unnecessary procedures.² History is a good teacher but does not promise that its lessons are fully embraced by proponents of new and lucrative business models. In 1992, an objective study published in the New England Journal of Medicine proved the connection between physician financial conflict of interest in imaging center ownership and dramatic increases in medically unnecessary procedures billed to the California workers' compensation system attributable to physician-owned imaging centers.³ In 2012, the California legislature examined physician-owned companies in the medical device industry and, arguably recognizing the same public health dangers as physician-owned imaging centers 20 years ago, now prohibits physicians from billing the workmen's compensation program for medical device products distributed by companies in which the surgeon has an ownership interest.⁴ This wisdom is not rationally limited to workers' compensation systems and applies broadly to items, services and goods reimbursed under federal health care programs and regulated by the federal anti-kickback statute.

Regulating physician financial conflict of interest and assuring strong enforcement and regulatory policies to avoid kickbacks or tainted self-referrals in the health industry is not advanced by allowing surgeons the opportunity to make extra income from the sale of products that they decide will be used in the performance of their own hospital procedures. Apart from the potential legal exposure for the surgeon, such a model also exposes hospitals to inordinate risk for compliance and risk management problems and exposes patients to the unacceptable risk of potentially unnecessary procedures. These concerns regarding the potential risk of abuse are not hypothetical but a realistic forecast based on over 40 years of federal health care fraud enforcement experience that has caused Congress to enact and expand anti-kickback and physician self-referral legislation and to fund a war on health care fraud since 1996. Physician-owned distributorships, like physician-owned imaging centers and other like arrangements, are déjà vu all over again for fraud, waste and abuse business practices negatively affecting publicly funded health care programs.

Medical ethics, sound compliance practices and current risk management standards compel the presumption that physician-owned distributorships violate the criminal, civil and

administrative provisions of the anti-kickback statute because it is not objectively reasonable to presume such arrangements operate, in practice, without regard in some fashion to a surgeon's referral leverage with a hospital. The anti-kickback statute's broad reach and "one purpose" legal standard for assessing the legal rationale of arrangements is likely violated in virtually every arrangement. Indeed, proponents of PODs do not deny the fundamental justification of POD arrangements is to achieve remuneration for surgeons that is related to procedures performed as part of their medical judgment.⁵

Some advocates of physician-owned distributorships and entities purport to have legal opinions approving such arrangements but this position does not diminish the serious doubt and ambiguity over the legitimacy of the various POD models that are proliferating in the medical device industry. The publicly available legal opinions and white papers, moreover, all acknowledge the anti-kickback implications of such arrangements and couch any approval in caveats that presume the *full implementation* of numerous and highly complex compliance safeguards. These legal positions supporting the formation of PODs further presume that there is "no intent" to violate the law by the physicians who own the entity or the hospital that contracts with the entity under the one-purpose test of the anti-kickback statute, but it is challenging to offer any credible justification for this model apart from the fact that it gives physicians the opportunity to earn profits that are derived solely from self-referrals.

It should be of significant concern to health industry stakeholders, the OIG and related enforcers and regulators that the promotion of physician-owned entities under the parameters of compliance safeguards and "model" provisions are wholly unproved. Enforcement experience tells us that such models are often a compliance house of cards that may collapse by a simple request to show *full implementation* of such compliance safeguards by the physician-owned entity. The legal risks inherent in the various models of physician owned entities caused the physician organization, the Association for Medical Ethics, to conclude that "*participating in PODs is both unethical and illegal and likely to ensnare physicians and hospitals in future enforcement activities and lawsuits.*"⁶

II. Physician-Owned Distributorships Undermine the Physician Gatekeeper Legal Safeguards.

The debate on the legal and policy legitimacy of PODs focuses on arguments of cost, value, healthcare savings, supply chain models, competition, conflict of interest, and fraud and abuse compliance. What is obscured in the justifications offered in defense of PODs is the seminal policy rationale that has driven legislative and enforcement policy, and in recent years, critical voluntary compliance and risk management efforts by health industry stakeholders and enhanced codes of ethics by medical societies and industry associations: the health care professional's role as the gatekeeper to medical utilization.

As Congress, government enforcers and medical ethics has long recognized, it is necessary to regulate physician compensation, ownership and investment activities because of the physician's unique and singular gatekeeper role in determining medical utilization that exists parallel to his or her financial interest in compensation and investment from their medical

decisions and medical interventions for the patient.⁷ Physician financial conflict of interest must be regulated because it is presumed harmful to the public interest. For this reason alone, the anti-kickback statute provides criminal and administrative sanctions even when a procedure tainted by a kickback is medically necessary and had a good patient outcome or when only one of many reasons for the arrangement is an illegal intent to seek or accept a kickback.⁸ Good rationales do not legally co-exist with bad actions under the anti-kickback statute for well-defined policy reasons. The conflict cannot be legally justified by medical necessity or good patient outcomes and cannot be cured by promised but unfounded healthcare savings outcomes. As the Senate Finance Committee aptly explained, “*even if the POD structure did lower healthcare costs, such an arrangement should not trump or justify violation of the anti-kickback statute or other Federal fraud and abuse laws.*”⁹

Physician-owned entities pose the greatest risk for unlawful financial conflict of interest because of physicians’ influence and leverage in both selecting products and using products in their own determined medical procedures. Physician involvement in hospital procurement negotiations and decisions over their own sponsored products is a scenario that presents grave risks to hospitals and physicians – risks that are not well managed by voluntary “model physician distributor guidance.” The POD business model challenges a red line that has been established by government enforcement actions, government compliance guidance, industry compliance guidance and medical codes of ethics. The fraud and abuse concerns cannot be superficially deflected as competitor concerns by device companies that do not want to contract with PODs. The Senate Finance Committee June 2011 report soberly notes its substantial concern over PODs: “[a] number of legal and ethical concerns have been identified as a result of this initial inquiry into the POD models . . . We believe it is incumbent upon the Committee to work with OIG . . . to effectively address the patient and program risks presented by PODs.”¹⁰ The Report further notes that, “[i]n effect, these entities act as a middleman entity that exists to give its physician investors the opportunity to profit from the sale and utilization of the medical devices they provide to hospitals.”¹¹

The emergence of PODs as a business model undermines the rationale for the anti-kickback statute and associated government enforcement efforts. It also undermines a decade of compliance progress by hospitals, physicians, and device companies that has promoted public health and societal interests in curbing financial conflicts that are barriers to the public’s access to affordable and high-quality healthcare. Transparency, disclosure, and the absence of self-interested physician influence on hospital procurement decisions are now hallmarks of good hospital business practices.

Until recently, the hospital community has largely been absent in the POD debate, but may be the most important stakeholder with the most at legal risk. PODs undermine the hospital management’s ability to control procurement objectively, manage tort liability, regulate its medical staff for compliance, and establish sound firewalls for financial conflict of interest. Doing business with PODs, moreover, is a *rebuttable* presumption of an illegal kickback to maintain or obtain physician procedures in the hospital that will always require explanation, express oversight and objective justification by hospital management and Board of Director members. As set out in greater detail below, the OIG has noted that PODs “should be closely

scrutinized under the fraud and abuse laws.”¹² CMS has further noted that physician-owned entities raise concerns of “possible program or patient abuse” and “*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.*”¹³ Hospital CEOs and Boards have many challenges and internally reviewing POD arrangements and managing against the risk of anti-kickback and false claims exposure in light of demonstrable government concerns will prove exceptionally challenging.¹⁴

One challenge will be responding to government inquiries. As a result of the Senate Finance Committee’s inquiry in June 2011, the OIG initiated a nationwide survey of hospitals that billed the Medicare program for spinal surgery procedures.¹⁵ The OIG survey and audit of PODs has focused on hospital arrangements and operations. The survey questions seek information on a number of factors that may have influenced a hospital to purchase spinal implants from PODs, including: cost savings on devices, quality of devices, clinical effectiveness, and preference of surgeons.¹⁶ The OIG sought to know what benefits hospitals may derive from the POD distribution model.¹⁷ It also inquired whether a hospital had a policy in place that requires physicians to disclose any ownership in medical device companies and whether that information is provided to patients, and finally, what other services the hospital purchases from PODs.¹⁸

Also in response to the Senate Finance Committee’s report, the OIG issued a letter in September 2011 which detailed the agency’s plan to further evaluate and scrutinize “the recent proliferation of physician-owned distributorships.”¹⁹ Specifically, while declining to broadly address the Committee’s question on the legality of this model, the Inspector General noted that:

“the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute an illegal inducement under the Federal Anti-Kickback Statute. When evaluating the legality of such an investment, OIG would consider, among other factors, the terms under which a physician may invest in the entity . . . ; the actual return or projected return on the physician’s investment; and the amount of revenues generated for the entity by its physician-investors.”²⁰

It is no surprise but hardly credible that POD proponents have asserted that the OIG letter effectively blesses certain PODs by not categorically declaring them illegal *per se*. This is a low bar for legally compliant arrangements and gives no comfort to physicians or hospitals assessing risk. Indeed, the OIG indicated that it will take enforcement action against physician-owned entities when appropriate, citing a July 2010 settlement involving the solicitation and receipt of remuneration from various hospitals by certain lithotripsy, urology, and prostate entities in exchange for the referral of Medicare beneficiaries controlled by the entities’ physician-owners.²¹

Building on this initial response, the OIG issued a Special Fraud Alert and related report on the impact of PODs from both a legal and cost perspective. In its March 2013 Special Fraud Alert, the OIG declared that PODs are “inherently suspect” and described “specific attributes and

practices of PODs that . . . produce substantial fraud and abuse risk and pose dangers to patient safety.”²² These features included:

- physician-owners conditioning referrals to hospitals and ASCs on the purchase of POD devices through coercion or promises of referrals;
- physician-owners being required, pressured, or actively encouraged to recommend or arrange for the purchase of POD devices;
- physician-owners facing repercussions for failing to use POD products; and
- PODs retaining the right to repurchase physician-owners’ interests for failure or inability to arrange for the purchase of POD products.²³

Nevertheless, the OIG explained that a POD can still violate the anti-kickback statute if only some or none of these elements are present.²⁴ It also emphasized that liability for unlawful arrangements flows both ways: “because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible ‘kickback’ transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute . . . [when the purchasing decision is made] to maintain or secure referrals from the POD’s physician owners.”²⁵

Adding data to its legal analysis, the OIG released a report on October 23, 2013 regarding the costs of PODs.²⁶ This report directly refuted claims of cost-savings by POD advocates, finding that most products cost relatively the same, while spinal plates cost nearly \$850 more on average when purchased through a POD.²⁷ More importantly, the OIG found that hospitals purchasing from PODs performed over 28% more spinal surgeries than hospitals that did not, and these hospitals experienced a threefold increase in the growth rate of spinal surgeries (16% v. 5%).²⁸ The OIG further concluded that most disclosure policies related to PODs were insufficient to give adequate notice to patients regarding a surgeon’s interest in a medical device company. Just 8% required disclosure to patients and of the 65% that required some form of disclosure to the hospital itself, this was typically required at the initial credentialing or hiring phase.²⁹ Ultimately, this report shows that cost-saving measures championed by PODs were a myth, while the very real concerns regarding overutilization and medically unnecessary services accord with the aggregate hospital data.

As a result of these numerous studies and legal analyses, the OIG’s measured approach to assessing the impact of PODs, has well-positioned the agency for future prosecution and litigation activities focused on the structure and operation of PODs for the contracting parties.

Given the OIG guidance, DOJ enforcement history and Congressional concern, hospitals and health systems, individually and collectively, have a strong incentive to assess PODs both for traditional fraud and abuse risk but also under enterprise risk management (“ERM”) standards to assure that policies are in place that require transparency, disclosure and documented risk assessment and mitigation. In addition to fraud and abuse risks, there may be increased risks for class actions, negligence suits and competition challenges related to

procurement arrangements with PODs.³⁰ Further, identification of physicians participating in PODs will be a simple task for government enforcers and plaintiffs' attorneys under the recently released Sunshine Act provisions.³¹ Many PODs will likely be required to report physician ownership interests in these entities, and when such data becomes available to OIG or the public, interested parties will be better able to tie negative treatment outcomes to inappropriate physician financial incentives. In courts and administrative tribunals, this could be a compelling argument for imposing liability – not only against the individual physician whose judgment was impaired, but against the hospital or ASC that failed to avoid these types of arrangements and failed to adequately comply with federal guidance. As such, hospitals and similar entities that purchase from PODs or give privileges to physician-owners are at substantially greater risk, both civilly and criminally.

Some hospitals perceive this risk and have acted to implement clear policies for their medical staff. Providence Health & Services, a health system that operates in several jurisdictions, notably in 2012 approved a policy that prohibits generally the purchase of items and services from physician-owned vendors (POV) that are owned or controlled by physicians on their medical staff or their immediate family members, citing the OIG determination that such arrangements are highly suspect and subject to scrutiny.³² Similarly, Hospital Corporation of America (HCA), the world's largest private operator of health care facilities in the world, recently enacted a policy that discourages any of its affiliates (both hospitals and free standing surgical centers) to conduct business with a POV.³³ Other hospitals have taken steps to prohibit or regulate PODs.

III. The Legal Question: PODs are Okay If Carefully Crafted...?

Advocates of physician-owned distributorships do not deny the anti-kickback implications of the various POD business models but argue that such business models may exist under the anti-kickback statute *if carefully crafted*.³⁴ Further, innovation and lower product costs are ostensibly promoted by PODs competing with the outdated industry distributor model that structures impenetrably high mark-ups of products sold by manufacturers.³⁵ Of course, the rise of POD formations by surgeons also coincides with a perceived unfairness in the decrease in Medicare reimbursement from federal health care programs in the last few years.³⁶ PODs may provide some surgeons with significant income tied directly to their medical determinations of surgical intervention and use of their own product in patient procedures.

In 2011, the American Association of Surgeon Distributors (AASD) was formed by physicians with POD ownership interests, "as a response to an expressed desire of surgeons, hospitals, and implant companies to have a means of qualifying ethical entities committed to positive patient outcomes and healthcare savings."³⁷ Its mission is to "promote healthcare savings through the advancement of legally compliant surgeon owned distributorships."³⁸ The AASD lists standards and policies pertaining to transparency, disclosure and anti-kickback compliance.³⁹ Whether PODs demonstrably promote healthcare savings or not does not diminish the anti-kickback and other risks associated with the business model. In fact, it is not even the right question for entities committed to legally compliant arrangements.⁴⁰

Advocates of the various physician-owned entity models argue, in addition to cost savings, that POD arrangements are no different than other arrangements such as physician-owned laboratories or ambulatory surgical centers (ASC). This argument is quite superficial. Physician-owned ASCs and laboratories are highly regulated for clinical and Medicare participation standards and part of the anti-kickback statute's safe harbor guidance. In contrast, POD arrangements have not been the subject of CMS or OIG programmatic review and are not regulated for Medicare participation. A Medicare beneficiary is unprotected as a patient in POD arrangements and likely is quite unaware of any voluntary professional standards or even disclosure of the POD arrangement. Business arrangements that are unethical and presumptively violative of the anti-kickback statute, moreover, are not likely to put patient notice and disclosure on the list of operational priorities. Of course, this point can be debated endlessly by lawyers but the OIG and Congress should ask: why should patients be at any risk from the foreseeable dangers of POD arrangements? Who speaks for the patients when their physician has a conflict of interest or kickback compliance issue associated with their care?

Advocates further argue that POD arrangements are no different than health care professional compensation from research, education, and product training activities funded by industry, which should be viewed as a similar impermissible conflicts of interest. Industry support for research and education activities are separately compensated *bona fide* activities wholly unrelated to the exercise of independent medical judgment. In contrast, POD arrangements are more akin to physicians getting a piece of the action from their own surgical self-referral by leveraging compensation for the product they choose to use in their own surgeries.

Physician ownership or investment interests in laboratory, durable medical equipment, home health, imaging equipment, hospitals, ambulatory surgical centers and pain clinics have a well documented history of successful enforcement actions for anti-kickback, regulatory and billing violations.⁴¹ PODs similarly foster many of the same negative consequences associated with non-compliance with the anti-kickback statute: overutilization, unfair competition, conflict of interest, and billing irregularities. Such a relationship cannot be legally or ethically managed within the confines of the anti-kickback statute or codes of ethics that do not permit physicians to profit from their medical decisions related to patient care. The OIG has explained that, “[g]iven the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers, we believe these ventures should be closely scrutinized under the fraud and abuse laws,” and that, “[w]e believe all industry stakeholders involved in joint ventures with physicians, including medical device manufacturing and distribution entities, are well-advised to pay close attention to [OIG] guidance.”⁴²

The legal foundation for these concerns is not new. On its face, the federal anti-kickback statute prohibits the exchange of anything of value, cash or otherwise, for referrals, arrangements for furnish items or services, *or* for purchasing or recommending any good, facility, or service for which payment may be made under a Federal health care program.⁴³ Notably, the law punishes both sides of the transaction, both those offering or paying kickbacks and those soliciting or receiving them.⁴⁴ Fundamentally, for physicians, any remuneration for the exercise of medical judgment implicates the anti-kickback statute and that premise is a long standing

judicial interpretation of its purpose.⁴⁵ Congress, of course, has authorized OIG over the years to issue a number of safe harbors which recognize specific business practices that will not be prosecuted under the anti-kickback statute if compliant with each and every requirement set forth in the safe harbor.⁴⁶ There is no safe harbor, however, for POD arrangements. All POD arrangements are legally unprotected under the anti-kickback statute.

Moreover, OIG has long been wary of so-called “sham transactions,” arrangements that appear to be structured to meet the four corners of a relevant safe harbor, but are otherwise intended to transfer prohibited remuneration. Since 1994, OIG has noted that because of the ability to manipulate safe harbors in ways OIG has not contemplated, it seeks to prevent sham arrangements from receiving the protection of safe harbors.⁴⁷ The OIG has repeatedly emphasized that in reviewing an arrangement for compliance with safe harbor requirements:

We will evaluate both the form and substance of arrangements. To be protected, the form must accurately reflect the substance. . . . If a sham contract is entered into, which on paper looks like it complies with these provisions, but where there is no intent to have the space or equipment used or the services provided, then clearly we will look behind the contract and find that in reality payments are based on referrals. Thus, these contracts would not be protected under these provisions. This same general principle would apply in determining compliance with other safe harbors.⁴⁸

Accordingly, an arrangement predominately or solely designed to take advantage of surgeons referral leverage in exchange for ordering or arranging for the purchase of certain medical device products raises serious fraud and abuse concerns because at their core, their primary purpose is to enable physicians to earn additional profits for referrals. The parties’ intent and the purpose of the statute rather than only the structure of the arrangements are the touchstones for the legal assessment.

While the anti-kickback statute requires a degree of intent (knowing and willful) to establish liability, recent laws including the Affordable Care Act, have effectively diminished that scienter requirement in the wake of conflicting case law on the statute’s intent requirements.⁴⁹ In particular, the Affordable Care Act added a provision which states that specific intent or actual knowledge of an anti-kickback statute violation is no longer necessary for conviction; rather, a defendant need only intend to violate the law generally.⁵⁰

Further, the purpose of the anti-kickback statute is to remove any financial element or incentive from a physician’s medical advice or medical intervention for a patient as such advice or intervention should be objective, independent and reliable. Of the anti-kickback statute, the former Inspector General of HHS, June Gibbs Brown, stated, “[the law] is the guarantor of objective medical advice for federal [sic] health care program beneficiaries and helps ensure that providers refer patients based on the patients’ best medical interests and not because the providers stand to profit from the referral.”⁵¹ The OIG has also described why kickbacks are so harmful in the healthcare industry: “they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair

competition by freezing out competitors unwilling to pay kickbacks.”⁵² While this Federal Register commentary analyzes contractual joint ventures (“CJVs”) between physicians and other entities, the concerns of CJVs are heightened with PODs. For instance, the OIG explains that a physician entering into a CJV with a supplier would be “receiving in return the profits of the business as remuneration for its federal program referrals.”⁵³ The only substantive difference is that in CJVs, physicians (or other referral sources) contract with an existing entity to provide inventory, while in PODs, physicians simply create an entirely new business to do the same thing.

Importantly, as discussed in the OIG’s 1989 Special Fraud Alert, a “legitimate reason” to enter into a CJV is “raising necessary investment capital.”⁵⁴ Consequently, ventures that do not seek to raise much investment capital are considered “questionable” or “suspect” because these ventures “. . . may be 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.”⁵⁵ The OIG has affirmatively declared that “some of these joint ventures may violate . . . the anti-kickback statute.”⁵⁶

Notably, one of the aspects most troubling Congress and the OIG about PODs is that physician investment – and therefore risk – in these ventures is typically minimal, on the scale of hundreds to thousands of dollars. These physician-owned entities, then, fail to meet reasonable standards of legitimacy and raise nearly the same set of concerns as CJVs. In fact, in response to the initial proliferation of physician-owned entities in 2006, the OIG specifically referenced its 1989 guidance on joint ventures, explaining further that, “*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.*”⁵⁷

IV. OIG Advisory Opinions on Anti-Kickback Compliance Do Not Support POD Models.

Over the years, the OIG has released a number of advisory opinions concerning potential improper relationships and ventures between physicians and other health care entities which may violate the anti-kickback statute.⁵⁸ Recently, the OIG issued Advisory Opinion 12-01 (2012), which blessed a group purchasing organization (“GPO”) purchasing supplies on behalf of participants who were owned by the same parent company as the GPO.⁵⁹ Citing the GPO safe harbor regulations, the OIG noted that, while concerned about the risk of abuse and waste associated with GPOs, this arrangement had put in place, “a number of protections to guard against these negative results.”⁶⁰ Specifically, the OIG found that the GPO was not incentivized to increase costs for two reasons: first, any administrative revenues in excess of the GPO’s costs were passed back to the participants, who had to report in turn these amounts as rebates/discounts.⁶¹ Further, the GPO was open to both affiliated participants (those owned by the same parent) and un-affiliated participants (those not associated with the GPO or parent company at all).⁶² The OIG, therefore, found that the GPO was incentivized through competitive forces to seek the lowest prices possible for its members. PODs, on the other hand, are often restricted to specific physician groups with privileges at only one or two hospitals. Likewise, PODs are not typically set up to return revenues to purchasers as discounts, but rather return

those amounts to the physician owners as profits. This incentive structure fails to put in place the protections that the OIG found necessary to reduce anti-kickback risk.

The concern with physician owned entities and investors was further emphasized in OIG Advisory Opinion 11-15 (2011), where the OIG declined to support physician investors in a pathology laboratory management company on the basis that the return on investment and compensation violated the anti-kickback statute, notwithstanding suggested compliance safeguards.⁶³ Similarly, in Advisory Opinion 04-17 (2004), the OIG analyzed a proposed arrangement whereby a physician group would own and operate a pathology laboratory.⁶⁴ The OIG concluded that this arrangement raised serious risks and could be prosecuted under the anti-kickback statute. Of particular importance to PODs, the OIG explained that:

. . . even if each of the individual agreements making up the Proposed Arrangement could satisfy the applicable safe harbor conditions under the space and equipment rental safe harbors and the personal services and management contracts safe harbor, the safe harbors would only protect the remuneration paid by the Physician Groups to the Requestor for actual services rendered or space or equipment rented. In the Proposed Arrangement, a *Physician Group's retained profit from the pathology services would not be protected by any safe harbor.*⁶⁵

Because of the unique ability of a physician to direct referrals (or purchase items) and the financial incentives involved, profits derived through an ownership interest in an upstream supplier or other ancillary service remain troubling for the OIG.

Several other Advisory Opinions issued by OIG throughout the years illustrate the legal problems with PODs and the significant risk of OIG sanctions associated with them. In Advisory Opinion 06-02 (2006), for instance, the OIG analyzed two proposed programs by which a durable medical equipment (DME) company would offer delivery management services to physicians.⁶⁶ Under the proposed arrangements, the physicians' financial incentives would directly align with those of the DME company, a fact the OIG found troubling: "[t]he proposed program offers physician practices the potentially lucrative opportunity to expand into the DME and orthotics business with little or no business risk and to retain a share of profits from DME and orthotics business generated by the physician practice."⁶⁷ Even with Federal health care programs carved out of the arrangement, the OIG still held that this program would generate unprotected, prohibited remuneration.⁶⁸ This analysis is directly comparable to PODs, which are offering physicians those same lucrative opportunities to expand into upstream markets, except under the POD model, physician distributors are not even bothering to carve out federal business.

Notably, the OIG further explained:

[t]he only significant difference between the first proposed program and the problematic contractual joint ventures identified in the Special Advisory Bulletin is the absence of Federal health care program business. The "carve out" of Federal business is not dispositive, however, on the question of whether the proposed program potentially violates the anti-kickback statute. . . . Thus, we

cannot conclude that there would be no nexus between the potential profits physicians may generate from the private pay DME and orthotics business and prescriptions of the Requestor's products for Federally insured patients.⁶⁹

Clearly, then, even if POD proponents attempt to carve Federal health care program business out of their model, the OIG would still recognize the inherent threat of physicians motivated by profit considerations, medically unnecessary services, and overutilization.

Even more recently, in Advisory Opinion 11-08 (2011), the OIG identified significant program risk stemming from physician financial interest in ancillary service industries: “[a]rrangements that closely tie DME suppliers to IDTF staff members, physicians with financial interests in the IDTFs who are in a position to prescribe, and patients . . . are particularly susceptible to problematic marketing schemes.”⁷⁰

Given the significant sway physicians have not only on patients, but also on hospitals, certain arrangements can cause those physicians to refer or recommend items and services contrary to their independent medical judgment.⁷¹ This is often known as “white coat” marketing, which the OIG describes as a practice in which “a physician or other health care professional is involved in the marketing activity . . . White coat marketing is closely scrutinized under the anti-kickback statute because physicians . . . are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services . . .”⁷² The risks of fraud and abuse when physicians are misincentivized are significantly compounded.⁷³

Other OIG Advisory Opinions further address the parameters of physician ownership or investment incentives and the ability to refer, all suggesting that arrangement elements of various POD models are legally problematic. For example, in Advisory Opinion 08-20 (2008), an arrangement in which a DME company was given access to hospital staff and patients avoided the anti-kickback statute prohibitions because no remuneration flowed back to the hospital and physicians capable of making referrals.⁷⁴ However, if physicians are also owners of the medical products, as the POD model would allow, the anti-kickback statute will be implicated, since referrals or recommendations will flow from the physicians to the suppliers and remuneration, vice versa, will flow from the suppliers back to those potential referral sources, in the form of profits and return on investment.⁷⁵ Such a practice appears contrary to the OIG's guidance.

Furthermore, the OIG has noted in Advisory Opinion 03-12 (2003) that one important way to reduce or mitigate the risk of fraud and abuse in joint ventures is to ensure that physician investors are not referral sources, thus limiting the potential for abusive, financially-motivated referrals.⁷⁶ Unfortunately for its proponents, however, the POD model crumbles without physician investors being the primary, and in many cases the only, source of referrals (defined broadly under the anti-kickback statute) to the POD entity. In addition, OIG regularly requires that any return on investment be directly proportional to the percentage of capital investment, and therefore risk, actually contributed by the physician investor.⁷⁷ Many PODs make the promise of a low-risk, high-reward system and require little legitimate capital contribution.

Suppliers can also mitigate the risk of fraud and abuse through providing freedom of choice to patients when selecting an ancillary item or service provider.⁷⁸ In Advisory Opinion 02-04 (2002), the OIG blessed an arrangement whereby a supplier would provide a list of local competitors to potential referral sources and encourage distribution of the list to patients deciding on a supplier.⁷⁹ The OIG, in addition, also required that the DME provider not rent a “consignment closet” nor make any payment whatsoever to its potential referral sources.⁸⁰ Under many POD models, moreover, patients are not informed when undergoing certain treatment that a POD is the supplier of the applicable items or services. Instead, hospitals are generally making these decisions, and may be subject to significant leverage from surgeons also operating PODs.

The OIG has consistently warned against physicians benefiting financially from referrals to ancillary service providers. In Advisory Opinion 99-13 (1999), the OIG stated that, “[n]or are we able to exclude the possibility that the physicians may be soliciting improper discounts on business for which they have the opportunity earn money in exchange for referrals of business for which they have no opportunity, but for which the laboratories can receive additional revenue.”⁸¹ In this scenario, physicians were backing into the revenue of laboratories because they couldn’t bill directly for laboratory services themselves.⁸² Similarly, in the POD model, physicians don’t have the opportunity to earn money from arranging for certain surgical hardware and other supplies unless they have an ownership interest in the relevant supplier. Of course, when physicians obtain such ownership interest, the data shows that procedures, and the associated costs of those procedures, increases substantially.

V. Physician Self-Referral Prohibitions Apply to PODs? Yes, They Do.

Separate from the anti-kickback statute, the Federal prohibition against physician self-referrals (commonly called the “Stark Law”) may also create a significant compliance risk for hospitals participating in POD relationships.⁸³ The Stark Law was originally developed to combat the inherent conflict of interest that develops when a physician, as the gatekeeper to medical utilization, maintains a financial relationship with the entities to which he or she refers a patient. In 1989, as a prelude to and support for the passage of the Stark Law, the OIG conducted a statistical study of the effects of self-referrals by physicians and found that physician financial interest played a major role in which services patients received, how much of those services were received, and who provided the services.⁸⁴ In its report to Congress, the OIG concluded that “patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services,” resulting in over \$28 million in bills to Medicare in 1987.⁸⁵ Unsurprisingly, these numbers led Congress to quickly enact the bill.

After the passage of the Stark Law, CMS began promulgating proposed regulations for comment. As CMS (known as the Health Care Financing Administration at the time) specifically noted:

We believe that [the Stark Law] was enacted out of concern over the findings of various studies that physicians who have a financial relationship with a laboratory entity order more clinical laboratory tests for their Medicare patients than physicians who do not have a financial relationship. There have been at least

10 studies conducted over the past few years that concluded that patients of physicians who have financial relationships with health care suppliers receive a greater number of health care services from those suppliers than do patients generally.⁸⁶

The Stark Law “*reflects the Congress’ unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives.*”⁸⁷ It is these illegitimate financial incentives that make PODs a significant compliance risk. CMS has further noted that the Stark Law was specifically enacted to “*address over-utilization, anti-competitive behavior, and other abuses of health care services that occur when physicians have financial relationships with certain ancillary services entities to which they refer Medicare or Medicaid patients. . . . Overutilization increases program costs because Medicare (or Medicaid) pays for more items or services than are medically necessary.*”⁸⁸ Even taking POD proponents’ word at face value that this model reduces the price of each device purchased, it ignores the larger problem that these items might not be necessary in the first place.

Legally, the Stark Law prohibits a physician from making a referral to an entity for “designated health services” (DHS) if that physician (or his immediate family) has a financial relationship with the entity, unless an exception applies.⁸⁹ The term “referral” is defined broadly to include any request or order by a physician for DHS or a physician certifying the need for DHS.⁹⁰ The term also includes the establishment of a plan of care by a physician which includes the provision of DHS.⁹¹ As well, financial relationship is also broad, including not just ownership, equity, or debt situations, but also direct and indirect compensation arrangements, whereby a DHS entity provides certain supplies, services, or other valuable consideration as payment for a referral.⁹²

While there is debate on the scope of Stark physician referral compliance as it relates to physician-owned entities in medical products, it should be assumed that POD physicians are making referrals for certain designated health services (inpatient and outpatient hospital services) to an entity in which they have a financial relationship (contracted hospital). Proponents of PODs argue that the indirect compensation exception may apply to shield the referrals from the scope of Stark.⁹³ Here, again, there is substantial doubt and high risk in assuming any Stark exception applies. The indirect compensation exception does not apply if there is any anti-kickback compliance violation and arguably is not applicable at all. The financial penalties for violating the Stark law are substantial. Accordingly, hospital management and hospital Boards will take a very large risk to simply presume no Stark and consequent False Claims Act potential liability exists with POD arrangements. Assuming the Stark law has no application to hospitals doing business with PODs is legally reckless.

VI. A Survey of Hospital Policies Show A Steady and Growing Concern Over PODs.

While the federal government has repeatedly noted its growing concern over the questionable incentives inherent in PODs, not all hospitals have unequivocally stated their opposition to doing business with these entities.⁹⁴ In fact, some facilities, cognizant of the risks

associated with PODs, have nevertheless entered into purchase agreements with physician-vendors.⁹⁵ Still, a large and steadily increasing number of hospitals are revising their policies and procedures to make it clear that their organization will not conduct business with physician-owned entities.

Noting concerns from the Senate Finance Committee and the OIG of PODs and related entities, which the government suggests may be illegal under the anti-kickback statute, major hospital chain HCA has implemented a broad and restrictive policy against purchasing any items or services for use in patient care from physician-owned entities.⁹⁶ The HCA policy applies to approximately 160 hospitals and 110 ambulatory surgical centers (ASCs) across the United States, as well as HCA's home health agencies, physician practices and other service centers. HCA's policy references the specific concerns of the OIG and the factors identified by the OIG which may result in a problematic relationship. It also acknowledges the "One Purpose Test" of the anti-kickback statute, whereby if any one purpose of an arrangement is to generate improper referrals or remuneration, the conduct is in violation of the statute, regardless of any number of positive off-setting purposes of the arrangement.

In addition, given its size, HCA appears to have structured its procedures so that it can protect itself from unwittingly doing business with a POD. The organizations' procedures require that purchases be made at fair market value for any and all vendors, and should a vendor be found to be a physician-owned entity during the purchasing process, the purchase must be specifically reviewed and approved by HCA's counsel.

Since the issuance of OIG's Special Fraud Alert, several notable hospital systems have issued policies and position statements on interactions with PODs. Ascension Health, LHP Hospital Group, and Tenet have each published guidance that prohibits their hospitals from doing business with PODs under most conditions. Tenet and HCA alone account for nearly 250 U.S. hospitals, demonstrating the swift proliferation of anti-POD policies throughout the country.

Likewise, other facilities have adopted similar policies, including Providence Health & Services, Tomball Regional Hospital, and Martin Memorial Hospital.⁹⁷ In the past two years, each of these facilities has identified the risks associated with PODs and affirmatively decided to avoid doing business with them. Scott Samples, spokesman for Martin Memorial, explained his facility's rationale: "[w]e were looking at the potential legality of [PODs] and trying to determine what we thought was in the best interests of Martin Memorial and decided to be very proactive and not participate in PODs."⁹⁸

Martin Memorial's policy bans entering into purchasing agreements with physician-owned intermediaries where physician ownership is in excess of 5% or the physician investor is affiliated with the hospital.⁹⁹ Tomball, which was recently acquired by Community Health Systems (see below), maintains a near-verbatim policy as HCA, noting the risk identified by OIG and discouraging the purchasing of any items or services from PODs.¹⁰⁰ Providence explains that due to the national scrutiny of the relationship between hospitals and physician-owned entities, no Providence-affiliated entity may purchase items or services from a POV where the POV owners or operators are physicians associated with Providence.¹⁰¹ Memorial Hospital in

Colorado states that it will not purchase any medical devices requested by a physician if that physician is receiving payment from the manufacturer of the device, unless such payment is reasonable compensation associated with a clinical trial.¹⁰²

Each of these health systems has taken specific affirmative steps to distance themselves and their purchasing practices from the specter of PODs. As the spokesman for Martin Memorial expressed, hospitals are not eschewing PODs for the fact that they do not represent a potential economic benefit for hospitals, but rather that any derived benefit is far outweighed by the substantial and apparent legal and compliance risks associated with physician-owned entity relationships.

Other hospitals have strong conflict of interest policies that while not directed at PODs would appear to prohibit such arrangements. Community Health Systems, for example, one of the largest hospital chains in the country with 120 locations in 28 states, explains in its Code of Conduct that:

[e]mployees should not have any personal interests or outside activities that are incompatible, or appear to be incompatible, with the loyalty and responsibility owed to the organization. Employees must avoid any outside financial interest that might influence decisions or actions in the performance of their duties for the organization . . . Potential conflicts of interest might include: A personal or family interest in an enterprise that has a business relationship with the organization or a facility.¹⁰³

Other hospitals have restricted and regulated associations with PODs, or have implemented broad conflict of interest policies ostensibly limiting such associations without stating so outright. For instance, University of Colorado Hospital requires that all vendor representatives disclose any financial relationships physicians or staffs of the hospital have with the representative's company.¹⁰⁴ Methodist Le Bonheur Healthcare, a regional system in Tennessee, places a duty on its employees to avoid conflicts of interest where their business decisions could be or appear to be influenced.¹⁰⁵ Importantly, many policies like Methodist's contemplate and outlaw even the appearance of impropriety.

Cognizant of the importance of a reputation for objectiveness in medical decision making and compliance with legal standards that many patients expect, hospitals have enacted policies intended to bolster such a reputation. For instance, Hardin Memorial Hospital in Kentucky and Hilo Medical Center in Hawaii have put policies into place concerning conflicts of interest with vendors, as well as policies calling for all purchasing to be completed in a commercial reasonable manner without exceeding what is necessary to accomplish legitimate business purposes.¹⁰⁶ However, while these policies are seemingly broad and sufficiently prohibitive, they may allow PODs when examined critically.

While few hospital systems have outright announced their association with a POD, it is believed that over two hundred hospital entities may be currently doing business with physician-owned companies. Palomar Pomerado Health in California narrated its internal review and

approval process of a purchase agreement with a POD through meeting minutes and quarterly reports.¹⁰⁷ Cognizant of the substantial risk involved, even to the point of requiring any agreement to contain a cease and desist clause should PODs officially become illegal, the Board Finance Committee of Pomerado approved of entering into a purchase agreement and was actively “supportive of the business reasons behind PODs.”¹⁰⁸ Of course, it is not usual for parties to have the right to cancel an illegal agreement when it is “officially” determined to be illegal. Whether the POD arrangement with Palomar meets recommended compliance safeguards is unknown.

VII. Recent Enforcement Action Demonstrates the Dangers of PODs

Recently, the federal government has intervened in at least two qui tams, directly challenging the legality of the POD structure. Though these cases have not yet been resolved, the government’s action indicates that it has taken – and will continue to take – an aggressive position on kickback arrangements involving PODs and their physician-owners.

In *United States ex rel. Cairns v. D.S. Medical, L.L.C. et al.*, filed in the Eastern District of Missouri, DOJ filed a five count complaint-in-intervention, alleging FCA violations premised on kickbacks, conspiracy, payment under mistake of fact, and unjust enrichment.¹⁰⁹ DOJ alleged that a neurosurgeon operated, and his fiance owned, a spinal implant distributorship in which his practice was virtually the company’s only client. The POD and the neurosurgeon’s practice shared common space, employees, contractors, and, most importantly, patients.¹¹⁰ The physician purchased implants exclusively from the POD, which bore almost no start-up or marketing expenses and little legitimate financial risk.¹¹¹

Not only structurally suspect, the financial impact of the POD arrangement was problematic. The hospital where the neurosurgeon regularly practiced, as well as the manufacturers providing the implants at issue, noticed that in the first month of the POD’s existence, the surgeon requested the purchase of over \$1.3 million of surgical implants and supplies.¹¹² His utilization rate was double that of his nearest local competitor.¹¹³ Not to be outdone, his fiance sourced these implants for purchase by the hospital, typically at rates significantly higher than the same product from a different vendor.¹¹⁴ When the hospital objected to these rates, the neurosurgeon directed his fiance in the renegotiation of the terms of the supply contract with the upstream vendors, regularly switching vendors when manufacturers would not – or could not – agree to certain pricing and commission requests. In the first two years of the POD’s existence, it earned net profits of 94% and 86%, with the fiance taking home nearly 31 times her income prior to owning and operating the distributorship.¹¹⁵

In addition to the alleged conduct and resulting financial impact, the government sought to show that the neurosurgeon and his fiance knew of the anti-kickback statute and the problems with their arrangement. The individuals refused to run the purchases of sporting tickets and travel through the POD accounts to hide the arrangement.¹¹⁶ Asked by both the hospital and manufacturers about their professional relationship and the compensation flowing between them, the neurosurgeon and fiance failed to disclose the nature of their arrangement.¹¹⁷ According to the government, the neurosurgeon “knowingly and willfully solicited and received remuneration

(including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind from [the POD] in return for ordering, arranging for, and recommending the hospital's purchasing and ordering of spinal implants for which payment was made in whole or in part by the Medicare and/or Medicaid programs."¹¹⁸

The United States recently made a similar intervention in a matter that has been at the forefront of the legal battle involving PODs. After the OIG published its Special Fraud Alert, Reliance Medical Systems filed a short-lived complaint against OIG alleging First Amendment and due process violations.¹¹⁹ Not to be outdone, the federal government filed a complaint in September alleging that Reliance and physician-owner Dr. Aria Sabit, as well as other physician and non-physician owners of Reliance and several related companies, engaged in kickback arrangements in the spinal implant market.¹²⁰ The complaint alleged that Reliance, its operators, and the physician-owners each submitted or caused to be submitted false claims and made false statements material to payment of claims, because each of the claims were tainted by kickbacks from Reliance to the physician-owners.¹²¹ According to DOJ, the Reliance operators would recruit neurosurgeons and, after a period of evaluation, invite them to become physician-owners for varying capital contributions.¹²² Typically, Reliance would pay to the physician the amount of the capital contribution or more before the physician became an owner, and the physician would then pay a certain amount back as a "buy-in."¹²³ The complaint explains that Reliance would then direct the physicians to apply significant pressure to their hospitals in order to compel the purchase of Reliance products and to avoid renegotiating prices, despite the fact that the products were commercially available.¹²⁴

DOJ's investigation into the arrangement alleges that Reliance and related PODs received approximately 99% of their referrals from investors, well exceeding the 40% threshold of the investment safe harbor.¹²⁵ In addition, physician owners moved at least 70% of their business to Reliance and related PODs when first becoming physician-owners.¹²⁶ Notably, the physician-owners did not disclose the arrangement to patients or hospitals and, when directly questioned by hospitals about their financial relationships with these PODs, affirmatively denied any involvement with the entities.¹²⁷

The physician-owners were paid as much as \$3.6 million for arranging for the purchase of POD products and those that did not adequately meet performance and financial quotas were pressured into higher production or forced to sell their ownership interest back to the POD operators.¹²⁸ Ultimately, the government alleged that at least five patients were harmed during or as a result of the surgeries performed by the physician-owners, including three patients who suffered post-operative infections and two who had post-operative complications and had to have implants removed through a second surgery at another hospital.¹²⁹

The government's intervention in these matters demonstrates its strong position against physician-owned entities and brings to life both the financial and patient impacts resulting from this practice. It also clearly signals that DOJ (and OIG) believe that POD practices are actionable under the anti-kickback statute and the FCA.

VIII. PODs by the Numbers: What Does the Data Really Show Us?

Much of the POD advocacy eschews lofty ideals of medical ethics and anti-kickback compliance, preferring to argue the numbers and costing savings of PODs. Notably, despite the arguments and limited unverifiable summary data from certain self-interested physicians groups and the American Association of Surgeon Distributors (AASD), there is no objective data to support a cost-saving rationale for physician owned entities that exist solely to provide unearned financial returns to physicians from product sales related to procedures performed predominantly in the hospital setting. Even if cost-savings could justify the financial conflict of interest, the public cannot realistically expect such cost-saving data to ever materialize if over 40 years of health care fraud enforcement experience is any guide.

The available data has clear bias. AASD, for example, conducted a cost study through the entity owned by the AASD board members, who are all orthopedic surgeons in California, and three area hospitals.¹³⁰ This study, which was conducted from May 2006 to May 2008, examined the potential cost savings a hospital could realize through a purchasing relationship with a POD for certain orthopedic implants, including screw and plate systems, knee replacements and hip replacements. The study ultimately concluded that hospitals, when purchasing these items, could save up to 34% of the cost of purchasing through traditional channels. Specifically, AASD examined its sales over the two year period, totaling \$2,058,217, and compared that to the projected cost of purchasing “equivalent” implants at the three hospitals’ average rate, which was \$3,099,192. AASD thereby concluded that the POD structure saved \$1,040,974 over the time period.¹³¹

Conversely, a study examining spinal fusion treatments concluded that increases in invasive and potentially medically unnecessary surgeries coincide with, and likely result from, the rise in physician-owned entities. This data is consistent with studies performed in other areas such as imaging centers owned by physicians.

In this study, cited by the Senate Finance Committee, researchers found that utilization rates of a certain medical procedure and associated medical device jumped 360% in one year after surgeons formed a POD.¹³² Analysts reviewed spinal fusion and refusion data from a certain hospital from 2002 to 2006; in 2005, spinal surgeons at the hospital decided to form a POD to sell the screws and rods used in these procedures. Prior to 2005, spinal refusions (where the first fusion fails) were steady at approximately 15-17 per year. In 2005 and 2006, surgeons associated with the POD performed 78 and 69 spinal refusions respectively. This was not associated with a similar rise in the number of initial spinal fusions, and, in fact, the rate of failure for initial spinal fusions (requiring refusion) increased from 2% to 11% in 2005.

Researchers pointed to two possible reasons for this sudden increase: first, that the refusions increased as a result of inferior quality screws and rods used during the first surgery that were sold by the POD, instead of the implants previously used which were ostensibly more effective; second, that the surgeons were performing medically unnecessary procedures in order to increase the use of their device and subsequent return. In spinal fusions, it is often the case that additional fusions will have to be done in the future. When this happens, the study supposes, instead of simply affixing the new rod and screws to the existing implant, the surgeons take out

the original implant from competing manufacturers altogether and implant an entirely new device from their own company.

The other studies, while addressing costs associated with PODs, are not independent, particularly the AASD study finding decreased costs as a result of physician ownership of the vendor. There, the researcher and the subject were the same entity, creating an obvious conflict and likely damaging the validity of the data obtained. While the POD did decrease costs relative to the hospital's average costs for similar items, the entity was acutely aware of its role as a test subject. Moreover, the study did not address whether any of the \$2,058,217 in fees was for items that were not medically necessary, which raises an important point: the concern with PODs is not only that the individual price of each item will rise, but rather that the sheer number of items and related procedures to implant those items will increase, thus affecting both healthcare costs and the harm and suffering of patients undergoing unnecessary medical treatment. The AASD study, moreover, does not demonstrate compliance with AASD voluntary compliance standards or identify whether any other legally recommended compliance standards were implemented.

IX. Conclusion

Physician-owned entities in the medical products arena present the same long-standing medical conflict of interest and anti-kickback concerns that always exist when physicians want to achieve additional financial gain in connection with medical procedures they have determined must be performed for their patient. Structuring economic advantage for product sales from the exercise of medical judgment is "any remuneration" under the anti-kickback statute. PODs do not exist to remedy the implant marketplace or to assure health cost savings for federal health care programs anymore than physician owners and investors in imaging centers, laboratories or lithoscopy clinics do. But, even if those ambitions could be achieved, they will not be justified by profits to physicians from medical conflicts of interests or improper financial arrangements with hospitals and device companies. Government policy makers and enforcers should recognize that the POD controversy is not about dueling data on implant costs. The public interest at risk is inherently far greater than the implant cost debate and cannot be deflected.

Hospitals should consider that POD arrangements substantially undermine compliance and risk management functions. Device companies that enter into POD arrangements are similarly challenged to maintain the extraordinary compliance enhancements that have occurred industry wide in the last several years in managing ethics, conflicts of interest and anti-kickback compliance. What hospital or device company CEO or member of a Board of Directors is willing to bet that any particular POD arrangement is fully compliant with the anti-kickback statute, or engage in oversight efforts to guarantee such compliance? What insurer wants to insure the risk hospitals face from POD arrangements in negligence and product liability situations?

~~The Who~~ (1971).

² In the physician administered drug arena, marketing the spread has been prosecuted as illustrated by the TAP Pharmaceutical Investigation that resulted in criminal prosecution of the company and several physicians in 2002; in the laboratory and pathology arena, physician compensation, investment and ownership has been disapproved in several OIG Advisory Opinions and prosecuted by the U.S. Department of Justice in numerous investigations in Florida and other jurisdictions since the 1990s; in the health care imaging sector, physician over-utilization patterns have been documented and such arrangements even banned in some jurisdictions.

³ See Swedlow *et al.*, *Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self-Referral by Physicians*, 327 New England J. of Med. 1502 (1992 (finding that 38% of MRI testing ordered by a "self-referring physicians" group was medically inappropriate and noting trends in Florida and California of high outlier rates of utilization of imaging services in centers owned by physicians).

⁴ S 863, 2011-2012 Leg., Reg. Sess., §6(c) (Ca 2012).

⁵ See Steinmann *et al.*, *Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model* (2009), available at http://www.hoganlovells.com/files/upload/Feb2009_SurgeonOwnershipDevices.pdf (hereinafter "Steinmann Study") (noting that PODs provide "a more fair compensation to surgeon" and that traditional supply methods "exert a negative influence on surgeon reimbursement.").

⁶ Association for Medical Ethics, *Bias – Physician Owned Distributorship (POD)*, <http://www.ethicaldoctor.org/physician-owned-distributorship> (last visited Jan. 15, 2013).

⁷ See Social Security Amendments of 1972, Pub. L. 92-603, 86 Stat. 1329 (1972).

⁸ See, e.g., *U.S. v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985) (setting forth the "one purpose test").

⁹ Attachment A, Minority Staff of S. Fin. Comm., 112th Cong., *Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight 4* (Comm. Print 2011).

¹⁰ *Id.* at 8.

¹¹ *Id.* at 2.

¹² Letter from Vicki Robinson, Chief, Industry Guidance Branch, Office of Counsel to the Inspector General, Office of Inspector General (Oct. 6, 2006), available at [https://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20\(2\).pdf](https://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20(2).pdf) (hereinafter 2006 OIG POD Letter).

¹³ Medicare Program; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians, 73 Fed. Reg. 23528, 23694 (Apr. 30, 2008).

¹⁴ While hospital management and executives may see short term benefits through association with PODs, boards of directors must actively monitor and assess risk and compliance for the institution. See *In re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996); see also *United States ex rel. Piacentile v. Merck & Co, Inc.*, No. 00-cv-00737 (E.D. Pa. final settlement announced Oct. 23, 2006). Moreover, recent Corporate Integrity Agreements entered into by the OIG have imposed substantial affirmative duties on board members to ensure oversight of compliance operations in health care entities.

¹⁵ See Nina Youngstrom, *OIG Noses Around Hospital Purchases of Spinal Implants from MD-Owned Entities*, AISHealth (Oct. 29, 2012), <http://aishealth.com/archive/rmc102912-02> (highlighting aspects of the OIG letter initiating the POD survey).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Letter from Daniel Levinson, Inspector General, Office of Inspector General (Sept. 13, 2011), available at <http://www.finance.senate.gov/newsroom/ranking/download/?id=eceb4bb0-c3da-4449-b8b3-d5715c63ef4e>

²⁰ *Id.* at 2.

²¹ *Id.*

²² Office of Inspector General, *Special Fraud Alert: Physician-Owned Entities* at 2-3 (March 26, 2013).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ Office of Inspector General, *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use* (OEI Report No. 01-11-00660) (Oct. 23, 2013).

²⁷ *Id.* at 9.

²⁸ *Id.* at 14.

²⁹ *Id.* at 13.

³⁰ This risk is substantially increased by the requirements that PODs publically report physician ownership interests and profits and payments under the “Sunshine” law and regulation. 42 U.S.C. §1320a-7h(a)(1)(A) *et seq.*; 42 C.F.R. §403.904 *et seq.*

³¹ *Id.*

³² See Attachment B, Hospital PODs Policy; see also Providence Health & Services, *Purchases from Physician-Owned Intermediaries/Distributors* (Feb. 9, 2012), available at <http://www2.providence.org/phs/integrity/Documents/PROV-ICP-723%20-%20Purchases%20from%20Physician-Owned%20Distributors.pdf>.

³³ See HCA, *Physician-Owned Vendor Relations* (Nov. 1, 2012), available at ec.hcahealthcare.com/CPM/LL027.doc.

³⁴ See Hooper Lundy & Bookman, *HLB Health Law E-Alert* (Sept. 22, 2011), available at http://health-law.com/wp-content/uploads/2011/11/POD_E-Alert_9-11.pdf (arguing that a “properly structured and operated” POD would not violate federal laws).

³⁵ See Steinmann Study, *supra* note 5 (explaining that current distribution methods are inefficient, far too costly, and lead to escalations in orthopedic implant prices).

³⁶ *Id.* (“[t]he costs of orthopedic implants continue to rise, over 13% annually, in a market in which hospital profit and physician reimbursement continue to decline.”).

³⁷ American Association of Surgeon Distributors, <http://aasdonline.org/> (last visited Dec. 28, 2012).

³⁸ *Id.*

³⁹ AASD Standards and Criteria for Surgeon Owned Distributor Membership:

a.) Distributorship must maintain a business structure consistent with all Federal Stark and Anti-Kickback statutes; b.) Distributorship must demonstrate merit by proving to be the lowest average cost vendor of like implants during a comparable contract period; c.) Annual price increases must not exceed 3% above the consumer price index (CPI); d.) Distributorship must demonstrate adherence to the AASD Product Evaluation Policy; e.) Distributorship must demonstrate adherence to the AASD Employee Training Requirements; f.) Distributorship must demonstrate adherence to the AASD Disclosure Policy; g.) Distributorship must demonstrate investment risk and compliance with the AASD Investment and Distribution Policy; h.) Distributorship must submit utilization data annually and is subject to audit; i.) Distributorship must not leverage referrals to any hospital or surgery center; j.) Distributorship must be a legitimate free standing stocking Distribution Company with employees, contracts, address, business license and insurance.; k.) Distributorship must have written contracts with hospitals and vendors for at least one year; l.) Distributorship pricing must not vary between hospitals.

⁴⁰ See Truhe, *Should Surgeons Be Encouraged to Take An Active Role In the Implantable Medical Device Supply Chain Through Physician Owned Entities?*, Food and Drug Policy Forum, Vol. 2, Issue 10 (May 2012). Mr. Truhe is the Senior Vice President and General Counsel for PDP Holdings, a physician-owned entity that seeks financial arrangements with industry for the use of device products in the physician investor surgeries. He argues a compliant physician-owned entity, in compliance with OIG anti-kickback guidance, would have the following minimal structure in place: No joint venture with a manufacturer or distributor; substantial capitalization, including the purchase of inventory and cost of case managers; investment return strictly proportional to investment; case support by personnel uninvolved in product sales; universal inventory of implants available for surgeon use with financial considerations excluded; surgeons use other company products when their product is not available; hospital product negotiations are conduct by entity management, not entity surgeons; hospital compliance program involved to assure transparency; utilization reviews; demonstrated cost savings; and, robust compliance training for surgeons. It is doubtful any physician owned entity meets this complex structure. Other advocates suggest that such arrangements must also be for fair market value, written agreement and prices that are equal or better than non physician owned

vendors. See Oppenheimer, Presentation, *Physician-Owned Distributors: To Be or Not to Be?* American Health Lawyers Association (Sept. 18, 2012).

⁴¹ Over 25 states, including California, Massachusetts, Maryland, Texas, and Florida, presently ban physicians from self-referring patients to diagnostic imaging centers in which they have an ownership interest, even if those patients are not covered by a Federal health care program. See Mark Friedman, *Doctor-Owned Imaging Center Raises Eyebrows*, Arkansas Business (08/25/08) available at <http://www.arkansasbusiness.com/article/41927/doctor-owned-imaging-center-raises-eyebrows?page=all>.

⁴² 2006 OIG POD Letter, *supra* note 12.

⁴³ See Criminal penalties for acts involving Federal health care programs, 42 U.S.C. § 1320a-7b(b) (2012).

⁴⁴ *Id.*

⁴⁵ See *U.S. v. Hancock*, 604 F.2d 999, 1001 (7th Cir. 1979) (physician decision to refer lab work for handling fees is basic element of corruption: "the potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds is plain, where the payments for the exercise of such judgments are added to the legitimate cost of the transaction"). See also *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995) (Congress introduced the broad term "remuneration" in the 1977 amendment of the statute to clarify the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid. H.R.Rep. No. 95-393, Pt. II, 95th Cong., 1st Sess. 53 reprinted in 1977 U.S.C.C.A.N. 3039, 3056. The phrase "any remuneration" was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates. The phrase "to induce" in § 1128B(b)(2) of the Act connotes "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.").

⁴⁶ *Id.*

⁴⁷ 59 Fed. Reg. 37202 (July 21, 1994).

⁴⁸ 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999) (citing 56 Fed. Reg. 35972).

⁴⁹ Compare Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(2), 124 Stat 119 (2010) with *Hanlester Network*, 51 F.3d 1390, 1400 (9th Cir. 1995) and *Ratzlaf v. United States*, 510 U.S. 135 (1994).

⁵⁰ Affordable Care Act § 6402(f)(2).

⁵¹ Press Release, Inspector General Announces Eight New Anti-kickback Statute Safe Harbors, Office of Inspector General, Nov. 18, 1999 available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/safenr.htm>.

⁵² 68 Fed. Reg. 23148, 23148 (Apr. 30, 2003).

⁵³ *Id.*

⁵⁴ 59 Fed. Reg. 65372, 65373-74 (Dec. 19, 1994).

⁵⁵ *Id.*; see also 56 Fed. Reg. 35969 (July 29, 1991) (noting that physician ownership increases the likelihood that a joint venture's primary purpose is to control a stream of referrals).

⁵⁶ 59 Fed. Reg. 65373-74.

⁵⁷ 2006 OIG POD Letter, *supra* note 12.

⁵⁸ See Attachment C, OIG Advisory Opinions Relevant to PODs (describing the conclusions and holdings of various advisory opinions issued by the OIG over the past decade which restrict or entirely condemn the use of certain joint venture models).

⁵⁹ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 12-01 (2012).

⁶⁰ *Id.* at 9.

⁶¹ *Id.* at 9-10.

⁶² *Id.* at 10.

⁶³ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 11-15 (2011).

⁶⁴ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 04-17 (2004).

⁶⁵ *Id.* at 7.

⁶⁶ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 06-02 (2006).

⁶⁷ *Id.* at 6.

⁶⁸ *Id.* at 1-2, 7.

⁶⁹ *Id.* at 7.

⁷⁰ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 11-08 at 6 (2011).

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 08-20 (2008).

⁷⁵ *See id.* at 5 (noting that despite "serious concerns," remuneration and referrals flow the same way).

⁷⁶ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 03-12 at 6 (2003).

⁷⁷ *Id.* at 7.

⁷⁸ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 02-04 at 2, 3 (2002).

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 99-13 at 5 (1999).

⁸² *Id.* at 2, 5.

⁸³ *See* 42 U.S.C. § 1395nn.

⁸⁴ Office of the Inspector General, U.S. Dep't of Health and Human Services, Financial Arrangements Between Physicians and Health Care Businesses, OAI 12-88-01410 (May 1989).

⁸⁵ *Id.* at iii.

⁸⁶ Physician Financial Relationship with, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements, 60 Fed. Reg. 41,914, 41,923 (Aug. 14, 1995) (codified at 42 C.F.R. pt. 411).

⁸⁷ 66 Fed. Reg. 856, 862 (Jan. 4, 2001).

⁸⁸ 69 Fed. Reg. 16054, 16124 (Mar. 26, 2004).

⁸⁹ 42 U.S.C. § 1395nn(a).

⁹⁰ *Id.* at § 1395nn(h)(5)(A).

⁹¹ *Id.* at § 1395nn(h)(5)(B).

⁹² *Id.* at § 1395nn(a)(2).

⁹³ 42 C.F.R. §411.357(p). *See also United States ex. rel Drakeford v. Tuomey Healthcare System Inc.*, No.10-1819 (4th Cir. 2012) (considering the scope of the Stark law and the application of the indirect compensation exception).

⁹⁴ *See generally* Attachment B, Hospital PODs Policy.

⁹⁵ *Id.*

⁹⁶ *See HCA, Physician-Owned Vendor Relations* (Nov. 1, 2012), available at ec.hcahealthcare.com/CPM/LL027.doc.

⁹⁷ Attachment B, Hospital PODs Policy.

⁹⁸ Rep. on Medicare Compliance Vol. 20 No. 22 at 2 (June 20, 2011).

⁹⁹ Martin Memorial Health Systems, Inc., *Physician-Owned Intermediaries* (May 6, 2011), available at <http://www.hoganlovells.com/files/Uploads/Documents/Hospital%20Policy%20on%20Physician%20Owned%20Intermediaries.pdf>.

¹⁰⁰ Tomball Regional Hospital, *Physician-Owned Vendors* (July 2010), available at

<http://www.tomballregionalmedicalcenter.com/PhysicianPortal/Documents/phy-OwnedVendors.pdf>.

¹⁰¹ Providence Health & Services, *Purchases from Physician-Owned Intermediaries/Distributors* (Feb. 9, 2012), available at <http://www2.providence.org/phs/integrity/Documents/PROV-ICP-723%20-%20Purchases%20from%20Physician-Owned%20Distributors.pdf>.

¹⁰² Memorial Health System, *Business Transactions Policies*, available at

http://www.memorialhealthsystem.com/wps/wcm/connect/bcb5f20040f5853da456ff74e1e6f338/MHS_BusinessTransactionPolicyHandbook.pdf?MOD=AJPERES&CACHEID=bcb5f20040f5853da456ff74e1e6f338 (last visited Dec. 28, 2012).

¹⁰³ Community Health Systems, *Code of Conduct 7*, available at

http://www.chs.net/company_overview/Code%20of%20Conduct%202012.pdf (last visited Dec. 28, 2012).

¹⁰⁴ University of Colorado, *Vender Representative (VR) Policy* (Nov. 2008), available at

http://www.uch.edu/docs/pdf/Vendor_Policy.pdf.

¹⁰⁵ Methodist Le Bonheur Healthcare, *Standards of Conduct: A Guide to Compliance* (Jan. 2007), available at

http://www.methodisthealth.org/static/files/1170349225494/SOC_Vendor.pdf.

¹⁰⁶ *See Hardin Memorial Hospital, Code of Ethical Business and Professional Behavior 2* (Nov. 1995, rev. Aug. 2009), available at

<http://www.hmh.net/ContentMgmt/uploads/Documents/Code%20of%20Ethical%20Business%20and%20Profession>

al%20Behavior.pdf; *see also* Hilo Medical Center, *Non-Physician Arrangements* (Aug, 2007), available at http://www.hhsc.org/easthi/hmc/procurement_documents/ResourceLibrary/PDFs/850-101-31%20Non-Physician%20Arrangements.pdf.

¹⁰⁷ Palomar Pomerado Health, *Board Finance Committee Meeting Minutes 4* (Aug, 29, 2011) available at http://www.palomarhealth.org/media/BoardMeetings/min_20110829_1140.pdf.

¹⁰⁸ *Id.*

¹⁰⁹ Complaint-in-intervention at 17-21, *U.S. ex rel. Cairns et al. v. D.S. Medical, LLC et al.* (E.D. Mo. July 7, 2014) (No. 1:12 CV 00004).

¹¹⁰ *Id.* at 7.

¹¹¹ *Id.* at 10.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at 12.

¹¹⁵ *Id.* at 14-15.

¹¹⁶ *Id.* at 16.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 17.

¹¹⁹ Complaint, *Reliance Medical Systems, LLC v. HHS-OIG* (C.D. Cal. Oct. 8, 2013).

¹²⁰ Complaint, *United States v. Reliance Medical Systems, LLC et al.* (C.D. Cal. Sept. 8, 2014) (CV14-6979).

¹²¹ *Id.*

¹²² *Id.* at 32-36.

¹²³ *See id.* at 27-28.

¹²⁴ *Id.* at 48-49.

¹²⁵ *See, e.g., id.* at 27.

¹²⁶ *Id.* at 29.

¹²⁷ *Id.* at 30-31; 42-43.

¹²⁸ *Id.* at 36-39.

¹²⁹ *Id.* at 63-70.

¹³⁰ *See generally* Steinmann Study, *supra* note 5.

¹³¹ *Id.*

¹³² Quality Implant Coalition, *Physician-Owned Implant Companies: Evidence of Product Quality Deficiency and/or Overutilization at One Hospital 1* (Nov. 2009), available at http://www.hoganlovells.com/files/upload/PODWhitePaper_Nov2009.pdf.