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SHOULD SURGEONS BE ENCOURAGED TO  
TAKE AN ACTIVE ROLE IN THE IMPLANTABLE  
MEDICAL DEVICE SUPPLY CHAIN THROUGH  
PHYSICIAN-OWNED ENTITIES?

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# Should Surgeons Be Encouraged to Take an Active Role in the Implantable Medical Device Supply Chain Through Physician-Owned Entities?

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## I. INTRODUCTION

In February 2012, a Government Accountability Office (GAO) study requested by the U.S. Senate Finance Committee confirmed what the hospital industry already knew—the lack of transparency in the pricing of surgical implants, coupled with the cultivation of physician preferences by the few major manufacturers, results in widely variable prices, lack of negotiating power on the part of hospitals, and the inability to align physician and hospital interests in restraining costs. Against this backdrop, physicians have seized the opportunity to enter the supply chain through ownership in entities taking a number of forms, threatening the market power of major manufacturers and attracting the attention of regulators. Congress has requested additional regulatory guidance from the Department of Health and Human Services' Office of Inspector General (HHS OIG), perceiving potential abuses from the unrestrained growth of physician entities not structured to avoid incentives to compromise quality and increase costs.

In this article, we will explore the structure of the \$10 billion market for orthopedic surgical implants, the distribution method of the few major manufacturers and the resulting issues. Next, we will review the regulatory and other issues presented by some of the physician-owned alternatives to this supply chain, and the efforts of the legacy manufacturers to inhibit their growth. Finally, we will explore how existing and recent OIG guidance provides a partial, but limited, roadmap to a model navigating the fraud laws.

The article recognizes the HHS OIG's limitations with respect to guidance regarding the application of the anti-kickback statute to the wide variety of structural and operational features of physician entities. The article concludes, however, that the OIG has available guidance options that would be extremely useful to the industry in structuring compliant physician-owned supply chain entities, and that a robust, physician-driven alternative model will lower barriers to entry for competing device manufacturers, introduce price competition, and facilitate the alignment of hospital and physician interests in cost containment. Congress and the Centers for Medicare & Medicaid Services (CMS) could contribute to this effort with legislation or regulations limiting price confidentiality in device supply contracting.

## POLICY RECOMMENDATIONS

- The HHS OIG should provide guidance in the structuring of physician-owned device entities utilizing the Special Fraud Alert model to distinguish between ideal and problematic structural and operational features, and, in particular, the independence of such entities from all manufacturers and their distributors.
- Congress or CMS should mandate transparency in the pricing of surgical implants, prohibiting confidentiality provisions that prevent competitive negotiation and hospital/physician cooperation in cost-containment efforts.

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## II. BACKGROUND

The existing model for the supply of surgical implants such as spine fusion hardware and total joints is something no one interested in cost containment or healthy competition would design. Manufacturers and their highly commissioned sales representatives with quotas, and regional distributors at risk of losing their territory, together cultivate physician loyalty with means both fair and foul to induce selection of what are referred to as physician preference items; that is, products as to which a surgeon can largely dictate purchase by the hospital from a particular manufacturer. The hospital is left to negotiate the acquisition cost of a product that has already been “sold” with no bargaining leverage, quite by design. The “legacy” supply chain is inefficient, ineffective, subject to abuse, and structured to inhibit cost competition and the free exchange of information about available products and alternative manufacturers. The distributor/sales representative model can add 40 percent and more to the hospital cost, on top of the premium built into the base price of brand-name products from the dominant manufacturers.

The legacy system has been “diagnosed” as fatally flawed, and the healthcare industry is exploring alternatives to gain control of implant costs through the cooperation of surgeons with respect to preference items. Hospitals in a position, through employment or otherwise, to control physician preferences have begun to exercise that power with mandatory device formularies and inclusion of physician preference items on group purchasing organization (GPO) schedules from which they have traditionally been excluded. Physician-owned manufacturers, distributorships and regional GPOs have emerged, leveraging physician device selection to obtain favorable pricing, at least some of which is being passed on to hospitals. These models take many forms, but many merely insert physicians into one or more stages in the existing, flawed supply chain, and suffer from regulatory flaws themselves because of ties to alternative manufacturers or structural designs that provide unacceptable opportunities for abusive behavior with respect to device selection or hospital contracting. They do, however, threaten the margins of the major manufacturers, who have, to date, been unsuccessful in lobbying for legislative or regulatory changes to eliminate the perceived competition. They have, on the other hand, accurately described some of the characteristics and regulatory flaws of some physician-owned models, while also overstating or mischaracterizing others, and pointedly attempting to paint all models with the same brush of suspicion.

The HHS OIG had, until recently, provided limited guidance since the emergence of physician-owned entities, essentially only confirming that the traditional anti-kickback analyses, including the suspect joint venture guidance, applied equally to physician device models, and declined to issue any position specific to same. In response to last summer’s request from the Senate Finance Committee, the OIG noted that guidance is difficult to issue as to the anti-kickback statute, but implicitly recognized that compliant entities could be created if properly structured with appropriate operational safeguards and conduct of the physicians and management with respect to manufacturers and hospitals. This guidance, however, has not succeeded in bringing enough clarity to the issue to allow physician models to overcome regulatory doubt on the part of prospective partners, opportunistically fanned by the legacy manufacturers.

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### III. ISSUES IN DISPUTE

#### A. The current model for hospital acquisition of physician preference surgical implants is inefficient, anticompetitive and subject to abuse.

The current reimbursement system for orthopedic surgery involving implantable physician preference items requires the hospital to acquire the selected device directly from the manufacturer and recover that cost in the charge to the patient or payor. As a result of this system, the surgeon is largely indifferent to the hospital's cost; and efforts to align surgeons' interests with those of the hospital have been largely unsuccessful.

The legacy manufacturers have employed a regional distributor/local sales representative system to market and promote their products. Distributors obtain regional territories and underwrite local sales representatives paid on commission to cover local markets, calling on physicians to show premium products representing the greatest margins to their manufacturers. Depending on the strategic value of the physician or group, the sales representative can arrange for the surgeon to be the beneficiary of a wide variety of lucrative arrangements, with key opinion leader, medical director, consulting, development, research and similar agreements paying hundreds of thousands of dollars to busy surgeons in large groups. At hospitals with multiple orthopedic surgeons and neurosurgeons, more than one manufacturer may have arrangements with different surgeons, precluding even the coordination of volume-discounting strategies by their hospitals. Regulators have attacked many of these agreements as thinly disguised kickbacks for loyalty to a single manufacturer. Additional inducements offered by sales representatives have been notorious, leading to "voluntary" codes of ethics by AdvaMed, the device industry trade association.

The legacy system's cultivation of physician loyalty is anticompetitive with respect to other manufacturers as well, given that the distributor/sales representative infrastructure is both expensive to build and effective in inhibiting access of smaller manufacturers to physicians already "locked in" to legacy companies.

The sales representative typically doubles as the surgical case assistant, providing valuable technical support to the surgeon and the operating room (OR) team. Unfortunately, the sales representative maintains his or her commission interest in the products used, and as a result, "upselling," or the encouragement to use additional devices or products in the course of surgery, is rampant, as is the practice of buttonholing surgeons in the halls in and around the surgical suites. Anecdotally, OR staff, and even some surgeons, resent the presence in the OR of a salesperson earning more than most in the OR suite.

The industry steadfastly defends the distributor/sales representative system as designed to provide the latest technological and clinical information directly from the manufacturer, to bring the highest-quality devices to the surgeon's patients, and to provide the highest-quality support to the surgical team, all despite the enormous additional cost of the supply chain. The industry defends the high margins from the fabrication line to the distributor by describing them as being necessary to support research and innovation.

#### B. Some initial physician-owned models implicate the fraud and abuse laws.

The market responded to the opportunities provided by the legacy system with the emergence of physician-owned entities inserting themselves into the supply chain in various ways. The generic model involves the creation of a supply chain entity that negotiates with one or more manufacturers to sell or consign selected products for resale to hospitals at which the surgeon-owners practice. The legacy industry attacked the models as representing disguised kickbacks for referrals from the surgeon-owners. Some models are affiliated with one or a limited number of manufacturers, implicating the OIG's joint venture analyses. Some are created by existing distributors, offering ownership interests in the existing or a clone (shell)

distributorship, likewise implicating joint venture scrutiny through attribution to the represented manufacturer. If badly structured, physician models can indeed fit the OIG's paradigm of joint ventures created for the transparent purpose of using ownership interests as just another variation on the theme of inducements for selection of the manufacturer's or distributor's products. The legacy industry responded to criticisms with a campaign to discredit so-called PODs (physician-owned distributors) by publishing articles suggesting that hospitals and physicians risked prosecution for clear violations of fraud and abuse laws, and attempting to persuade regulators and legislators to restrict their growth. The U.S. Senate Finance Committee's inquiry was the industry's most visible success in this endeavor, but the OIG's response presumably did not meet expectations, implicitly acknowledging that compliant models can be constructed.

### **C. Physician-owned supply chain entities do not inherently create asserted conflicts of interest with respect to the decision to operate or for device selection.**

The legacy industry similarly suggested, and the Senate Finance Committee surmised, that physician-owned entities would naturally lead to increased surgical volume as a result of the financial gain from the sale of implants, and to the selection of devices being influenced by considerations of profit. Putting aside the irony of concern for physician purity from an industry whose model historically cultivated physician loyalty with financial incentives, the suggestion that the physician-owned model presents conflicts of interest that are unacceptable can be challenged. While charges of "double-dipping" and making money in an enterprise from business you generate yourself have superficial logic, there are no regulatory proscriptions against either, and for good reason. Physicians make money from ancillary services in many settings, and the Stark law and regulations are the only existing limitations on self-referrals. Implantables necessarily associated with the underlying surgery are, if anything, less "ancillary" than other services or products and thus less subject to financially motivated referrals. The practice of medicine in a fee-for-service environment inherently involves a surgeon making money from his or her own "referral" of the patient for the underlying surgical procedure. The additional revenue, several orders of magnitude smaller, from the necessarily associated implants represents an implausible source of unacceptable financial motivation for unnecessary spine or joint surgery. It is relatively straightforward to guard against device selection being influenced by the model based on the model's design and operation.

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### **D. Compliant models share common structural and operational features.**

Experienced healthcare regulatory attorneys recognized the flaws in some of the emerging physician-owned companies, some of which, again, were nothing more than new models for the transfer of inducements by the legacy manufacturers and their distributors themselves. Insulating physicians from the opportunity to engage in improper leveraging of their surgical business with either prospective manufacturers or the hospitals at which they practice was an obvious first step. Total insulation of the physician entity from any ownership or relationship with a manufacturer other than as an arm's-length purchaser, while more complicated, greatly simplifies the anti-kickback problem by largely rendering irrelevant the OIG's joint venture cautions because no referrals to a joint venture with a Medicare provider take place (there being no such joint venture at all). The OIG's September 13, 2011, response to the Senate Finance Committee reflects the educational process in which it engaged, soliciting input from existing companies eager to describe the structure and operational features of their models. Although useful if only for confirming that there are no categorical fraud and abuse obstacles to physician ownership of device entities, the OIG response was short on specific guidance. The OIG noted that guidance as to the intent-based criminal anti-kickback statute is inherently generic, as violations are inherently more conduct related than they are structural.

## E. The OIG could bring clarity to the regulatory landscape with Special Fraud Alert-type guidance.

Notwithstanding the OIG's limitations with respect to specific guidance as to the key fraud and abuse issue applicable to physician entities, the September 13 letter did provide clues, at least referring to the relevance of structural and operational features and the conduct of the pertinent parties, while not actually describing same. While competent healthcare attorneys can look to extant guidance and deduce the roadmap to a compliant entity, the OIG's opacity permitted the legacy industry to persist in its efforts to maintain the specter of regulatory doubt through the industry media and direct access to physicians through distributors and sales representatives.

While the OIG's limitations regarding anti-kickback guidance are a given, the OIG is not without tools that could contribute to a regulatory environment in which all the players had a sufficient level of confidence in the parameters to make prudent decisions, at least relative to the context of the fraud and abuse laws in general. Rather than engage in the futile effort to provide safe-harbor-like affirmative guidance, the OIG could instead provide negative guidance using the Special Fraud Alert model to discuss the problematic structural and operational features specific to the device supply chain context that will likely invite scrutiny.

## IV. RESEARCH AND RESPONSE

Manufacturers engaged in fierce competition for the sale of very expensive products have employed a variety of strategies to reap the benefits of physician preference. With conferences at resort destinations, speaking fees, consulting agreements and medical directorships, manufacturers have sought to secure the loyalty of surgeons. It was perhaps inevitable that, given the amount of money at stake, abusive financial arrangements would surface. It was equally inevitable that such practices would attract the attention of regulators and prosecutors. The Department of Justice (DOJ) launched kickback prosecutions of orthopedic groups involved in allegedly fraudulent financial arrangements, and in 2007, entered into deferred prosecution agreements with four device manufacturers, which paid more than \$300 million in penalties.

The manufacturing industry responded with voluntary guidelines regarding many potentially abusive practices. Despite such efforts, abusive behavior persists. This past December, Medtronic agreed to a \$23.5 million settlement involving a program to pay surgeons \$1,000 to \$2,000 per patient to complete limited postmarket research on cardiac defibrillator implants. The broader healthcare industry responded with the emergence of PODs as an alternative to the existing model of physicians, subject to the influence of manufacturers, dictating that devices for hospitals be purchased with no accountability for cost.

A typical POD comprises physician investors from any number of surgical practices in a given market. The physicians evaluate a range of implantables offered by manufacturers that are willing to do business with them, and make selections based on quality and cost. Using the bargaining power associated with their own volume and their decision to standardize to a narrow range of devices, including generic alternatives to off-patent products, the POD negotiates a price that is more favorable than that at which any one hospital could purchase from the same manufacturer directly for isolated physician preferences. The POD approaches the hospital as any other vendor, with the favorable pricing in hand.

Such physician-owned entities are vulnerable to having their operations attributed to any manufacturers with which they are related or affiliated in any way. If the physician entity has such a relationship, federal regulators may view the creation of the venture itself as an inducement from the manufacturer to select its products, and may characterize it as merely another financial inducement. Such models merely add physicians to the traditional supply chain for no apparent reason and no evident value proposition, leaving the improper purpose (referrals) the likely suspect. Models including physician-owned manufacturers present an anti-kickback risk from the hospital's lack of an alternative source or price comparison.

Not surprisingly, major device manufacturers did not take the emergence of competition from PODs lightly, and attempted to use regulatory authorities and articles by industry attorneys to raise fraud and abuse concerns to discourage physician investment and hospital participation in PODs, while declining to sell their own products to physician entities, bootstrapping an argument that PODs limit device choices.

On October 6, 2006, the OIG issued a response to a request for guidance regarding physician investments in medical device industries. The requestor apparently asked simply whether the OIG's 1989 Special Fraud Alert on Joint Ventures applied to joint ventures in medical device distribution entities, and specifically asked the OIG to highlight some of the features of suspect joint ventures from that Alert that might apply to same. The letter itself contains its own limitation with respect to suggesting an inherent regulatory flaw in the POD model. Not only did the OIG decline to make any comment specific to PODs, the letter emphasized that the suspect joint venture guidance is not sector specific and applies equally to any joint venture involving physicians.

In Advisory Opinion No. 08-10 the OIG found problematic a proposed venture between an intensity modulated radiation therapy (IMRT) facility and its several referring urology groups. In an apparent attempt to secure a referral stream, the IMRT facility proposed to lease its equipment and personnel on a turnkey basis, allowing the urology groups to enter the IMRT business for profit by using their existing patient base. Continuing the theory advanced in the Special Advisory Bulletin on Contractual Joint Ventures,<sup>1</sup> the OIG concluded that the urologists were being offered the opportunity to expand into a new line of business (IMRT) with a captive referral base by an entity that would otherwise be a competitor in that same business. The artificially created opportunity to profit from the new line of business was seen as the inducement for continued patient referrals to the IMRT facility.

A medical device company seized the opportunity for comment on the proposed 2009 inpatient prospective payment system (IPPS) regulations to suggest that CMS respond to the prevalence of PODs and their alleged adverse impact on competition by deeming PODs to be HHS entities, which would preclude a POD from doing business with hospitals at which the physician investors performed procedures.<sup>2</sup> CMS declined, and instead solicited further comments on whether PODs were inherently problematic, or whether existing fraud and abuse laws were adequate to respond to abusive features and practices of particular PODs.

An April 2009 article entitled "PSSST, Have I Got a Deal for You," in the American Health Lawyers Association publication "Hospitals and Health Systems Rx," noted the lack of action regarding PODs by federal authorities and volunteered its own analysis of the anti-kickback and Stark implications of POD-hospital transactions, concluding that hospitals proceeded at their own risk. The anti-kickback argument was predicated on the transfer of an opportunity for profit from the physician investor's own referrals as prohibited remuneration, invoking the OIG guidance referenced above. As noted above, however, the hospital is not transferring an opportunity that existed in its hands to the POD. It is purchasing an item from a physician for value, not forgoing a business opportunity of its own and transferring same to the physician.

The industry effort to inhibit PODs has not been confined to the media or regulators. This May, the New Hampshire Senate rejected HB 1725, a physician implant self-referral ban that had passed the New Hampshire House in late March. HB 1725 would have prohibited physicians from referring any patient for a surgical procedure involving an implantable item or device if the physician has an ownership interest in any entity involved in the manufacture or distribution of the device. The New Hampshire Medical Society and others educated senators as to the anticompetitive motives of the sponsor of the bill (a still-active device representative) and the benefits of physician entities for hospitals, payors and patients. Consistent with the strategies discussed previously, some legacy manufacturers and their representatives had already begun to make reference to the legislation as evidence of regulatory hostility to discourage hospital and physician consideration of PODs. The defeat

of the bill in a state legislature demonstrates instead that the case for banning physician involvement in the device supply chain is less than persuasive to fully informed lawmakers.

In addition to the argument that the fraud and abuse laws are violated by PODs, opponents also invoke the supposedly apparent evil of physicians realizing income from a business where the demand is generated with their own decisions. Again, such arguments prove too much. The practice of medicine is the business of generating income from your own clinical recommendations. The fraud and abuse rules restrict certain self-referrals thought to be problematic and permit others, and preclude financial inducements from one party to another for referrals. If the fraud and abuse rules are not implicated, a generic appeal to conflict of interest principles should be unavailing. We expect physicians to recommend treatments and procedures unaffected by the financial incentives that are inherent in the practice of medicine in a fee-for-service market.

With respect to the underlying recommendation of surgery, the suggestion that the additional revenue from the sale of the associated implants will lead to increased surgical utilization is suspect. First, in legitimate models, the net amount available for distribution associated with the implants in any one surgical case should not be substantial in absolute terms if the entity is passing an appropriate portion of the savings from the model to the hospital acting as a prudent competitor. Given the relative magnitude of the professional fee for spine surgery, moreover, there should be no concern that any additional marginal income from the sale of implantables could influence surgical volumes themselves—the same analysis is used by the OIG with respect to ambulatory surgery centers and facility fee revenue to surgeon investors, with an even smaller disparity between the professional fee and the ancillary revenue in that setting.

**A. The HHS OIG should provide guidance in the structuring of physician-owned device entities utilizing the Special Fraud Alert model to distinguish between ideal and problematic structural and operational features, and, in particular, the independence of such entities from all manufacturers and their distributors.**

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The OIG, on September 13, 2011, submitted an interim response to the Senate Finance Committee’s request for guidance. The OIG notes that a wide variety of POD models and related entities exist, and that whether any particular entity poses any legal concerns depends on its particular characteristics. This statement itself makes clear that the OIG recognizes that such entities can be properly constructed. The OIG goes on to identify as critical factors “the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations.”

The OIG concludes the response by noting that actual behavior is the key determinant of regulatory compliance and that enforcement action against improper behavior will remain the OIG’s chief tool in combating abusive conduct. The OIG makes this point by referring to its recent enforcement action against a lithotripsy company, an otherwise common and compliant joint venture, whose physicians were alleged to have explicitly solicited favorable contract terms in return for continuing to refer patients to contracting hospitals.

It is clear that compliant models can be constructed consistent with the OIG’s September 13 comments and historical guidance. Fundamental to the joint venture guidance is the concern that the joint venture is simply a vehicle for an existing Medicare provider to transfer value, in the form of ownership distributions, to referring physicians. The guidance is a collection of features that reinforce the impression that the venture is a sham, in particular given that it contracts with the existing provider to perform the reimbursed services. The operative question is why, given that the provider is already in the relevant business and market, another business entity would be created to do the same thing, other than to use ownership by referring physicians to “launder” what would otherwise be prohibited inducements. While the time-honored approach of structuring joint ventures to avoid the problematic features identified in the Special Fraud Alert (nominal investments

financed by the provider, just for example) or meeting one of the available safe harbors is tried and true, it is submitted that another approach is available in the supply chain context that is vastly superior. Recalling that the underlying issue is created by the presence of a Medicare provider in the joint venture in a position to receive referrals from the physicians offered ownership interest, the entire joint venture analysis can be short-circuited by getting rid of the provider partner altogether.

It is submitted, for illustration, that a solo practitioner unilaterally undertaking to research implants, negotiating a cash on the barrelhead purchase from the manufacturer's loading dock, and negotiating a sale with a hospital at a price well below its historical cost cannot be accused of a kickback (assuming none is solicited from the manufacturer or the hospital—unlawful conduct as in the OIG's lithotripsy example). In other words, at least within the solo supply chain entity itself, a kickback is a theoretical impossibility. Stark may prevent self-referrals, but a kickback takes two parties. Adding a joint venture partner who provides only minority capital and perhaps accounting services, but is not reimbursed by Medicare, to a venture which itself does not bill Medicare, presumably yields the same conclusion.

Excluding manufacturers and their distributors from ownership is not sufficient, however. The anti-kickback concerns would re-emerge if a manufacturer reappeared as a contractual partner. The venture could then be characterized as a traditional distributor of the manufacturer and the creation of physician ownership interests could arguably be attributed upstream to the manufacturer. The OIG's contractual joint venture analysis would then put the venture right back where it started. In order to accomplish the sort of independence suggested above, the venture must be seen as doing the equivalent of having surgeons shop for implants at "Lowe's Home Spine and Joint Depot." Recapping the regulatory discussions above, and including the traditional joint venture safeguards for good measure, the structural and operational features of a compliant model, as alluded to by the OIG, would include:

- No joint venture with a manufacturer or distributor. Additional capital and operational services are provided by an entity with no reimbursable item or service business and no affiliation with any provider of any sort. Not a joint venture with any party connected in any way to a recipient of referrals. Total independence from manufacturers and their distributors. Agreement with manufacturer disclaims marketing and promotion duties, agency relationship, targets, quotas, minimum sales, territory, etc., and not commission based. Acts essentially as a mere "buyer's agent" for purchasing physicians only.
- Substantial capitalization: related to amount required to purchase expensive inventory, carry hospital accounts receivables, employ case managers and obtain office services. Surgeon investments are all cash, all equal and not financed. Return is strictly proportional to investment, which, in turn, is dictated by actual capital and operational requirements.

Case support is provided by an employee or contractor with no sales responsibility or incentive related to implant or surgical volume, and solely accountable to surgeon and OR team.

- Surgeons are exposed to universe of implants—management facilitates neutral and unbiased exploration and comparison of implants from any willing manufacturers presenting in a controlled environment in which financial considerations are excluded. Manufacturers may not "pay to play."
- Surgeons use other devices outside model where unavailable through model without limitation.
- Hospital negotiations are not conducted by surgeons, but rather by management. No communications by physicians with hospital personnel are permitted under compliance plan. Hospital purchasing personnel negotiate at arm's length, aware of savings potential from eliminated commissions and other costs. Physicians do not receive financial feedback regarding negotiation process, limiting any opportunity or means to engage in inappropriate behavior.

- The hospital compliance system engaged to ensure transparency and monitor appropriate behavior (including purchasing manager, CCO, CFO and general counsel for checks and balances).

Full disclosure to patients of physician ownership interest in entity supplying surgical implants.

- Utilization review—volume, case mix, indications, intensity, devices and manufacturers.
- Substantial cost savings. Anti-kickback statute almost explicitly requires savings in this context. Hospital must be assured of demonstrable and material cost savings as compared with alternative sources in order to purchase from referring physicians instead of such alternate sources. Paying more to a physician entity would obviously invite scrutiny. Fortunately, as the underlying products are commodities, ensuring such savings is relatively straightforward.
- Robust Compliance Program including training of physician investors and staff.

As discussed previously, the OIG’s limitations regarding anti-kickback guidance must be respected. The Senate Finance Committee’s desire for affirmative guidance was, in this respect, optimistic. On the other hand, the above discussion of the structural and operational features that can be incorporated into a physician-owned device entity suggest that the OIG could nonetheless provide extremely helpful commentary that would enable competent healthcare attorneys to provide counsel to their clients with as much confidence as they emit regarding other transactions that implicate the fraud and abuse rules. Even a discussion of the relevance of the traditional joint venture analysis to models that do not incorporate a device manufacturer as an owner or contractual partner would be helpful. Because Special Fraud Alerts do not create safe-harbor expectations on the part of counsel adopting or avoiding particular features, guidance in the form of “models which do, or don’t . . . create the appearance of improper intent and will be subjected to appropriate scrutiny,” is feasible even in the context of the anti-kickback statute, and would be immensely helpful to practitioners.

## **B. Congress or CMS should mandate transparency in the pricing of surgical implants, prohibiting confidentiality provisions that prevent competitive negotiation and hospital/physician cooperation in cost-containment efforts.**

The GAO report noted the adverse effects of strict pricing confidentiality in the device field, with dramatic difference in acquisition costs for the same items between hospitals, even after volume discount considerations. As also noted above, the anti-kickback statute almost directly requires that implants sourced from a physician entity must be accompanied with material savings. Because the items in question are commodities otherwise available in the market, obtaining them from physicians on *unfavorable* terms would almost compel an inference of improper inducement. Conversely, saving money by purchasing from physicians almost necessarily rebuts such an inference. The scrutiny of physician entity competition with the legacy manufacturers would obviously be facilitated with greater transparency in pricing. Even apart from the physician entity context, the ability of hospitals to compare pricing would bring some measure of balance to the negotiating table, currently tilted toward legacy manufacturers.

## V. IMPACT OF POLICY RECOMMENDATIONS

### A. The proliferation of physician supply chain entities would bring healthy competition to the market and both reduce cost and improve quality.

The legacy system creates a barrier to entry for smaller manufacturers with quality products, whether proprietary or generic to those of the major suppliers. These manufacturers can harness the physician model to deliver low-cost generic implantables, and facilitate bringing their proprietary products into the market with lower development and marketing costs. Competition from generics and proprietary products can only result in lower costs and higher quality for the healthcare marketplace. Even the legacy manufacturers could benefit if they chose to participate, as the existing system creates barriers to marketing products to physicians loyal to another manufacturer. Product evaluations open to all comers present at least the opportunity for “face time” with a broader pool of physicians than their sales representatives are currently fishing in.

### B. The physician model will facilitate increased collaboration between hospitals and physicians with respect to the cost of physician clinical decisions.

Even apart from innovative reimbursement models that invite physicians and others to form entities in a position to bundle all of the cost inputs for an inpatient admission or episode of treatment, such as the CMS Bundled Payment Initiative, or Accountable Care Organizations, the basic supply chain model, properly constructed, provides a unique opportunity to engage physicians with hospitals in a joint effort to control costs. Such alignment of interests has escaped the best efforts of the hospital C-suite to date, despite major expenditures of effort in the endeavor.

## VI. CONCLUSION

The cost of implantables has plagued the healthcare system for decades. The legacy model has contributed to the preservation of margins otherwise unsustainable in a competitive market and of barriers to entry by competing manufacturers. Alternative models have emerged that hold the promise of transforming the implantable market and bringing substantial cost savings to the healthcare system. Some of these models, however, incorporate features that could lead to the opposite result, and give rise to traditional fraud and abuse concerns. The OIG should contribute to the effort by providing guidance in the formation of such models to facilitate the proliferation of those that will bring lower costs and increased competition to the healthcare delivery system while guarding against those that do not hold the same promise.

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