



# SURGEON-OWNED DEVICE COMPANIES: A RISKY PROPOSITION

by

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Increasingly, medical device companies that manufacture or distribute implantable medical devices are creating passive investment vehicles to distribute profits to surgeons who implant such devices in patients. While the structure of these arrangements may differ from company to company, a common element is that investment opportunities and the resulting financial rewards are often being offered to surgeons because surgeons select the products. The resulting financial incentives are virtually invisible to patients, although they can clearly affect the treatment patients receive. These financial incentives pose serious compliance risks for physicians who invest in these types of companies. Moreover, hospitals and other facilities that do business with these companies because they are owned by referring physicians incur a substantial risk of violating the law.

The Advanced Medical Technology Association (AdvaMed), the trade association that represents many companies in the medical device industry, recently asked the HHS Office of Inspector General (OIG) to comment on these physician ownership schemes. In response, the OIG stated that “[g]iven the strong potential for improper inducements between and among the physician investors, [medical device and distribution] entities, device vendors, and device purchasers,” the OIG believes these types of ventures “should be closely scrutinized under the fraud and abuse laws.” *See* Letter from Vicki L. Robinson, Chief, Industry Guidance Branch, OIG, to Stephen J. Ubl, President and Chief Executive Officer, AdvaMed (Oct. 6, 2006).

The proliferation of surgeon-owned device companies is problematic for obvious reasons. What patient wants his or her surgeon to decide between a product from which the surgeon makes no money, and a product sold by the surgeon’s own company? What patient wants his or her hospital to feel compelled to do business with a device manufacturer owned by physicians who send it business? When a surgeon who profits from every use of a particular medical device is faced with a decision whether to select that device, a competing device, or perhaps no device at all, the surgeon’s financial interests may influence, and possibly corrupt, the treatment decision.

The typical genesis and structure of these arrangements is as follows: A small group of founders, who may or may not themselves be physicians, establish a company to manufacture or distribute medical devices for implantation in orthopedic surgeries. The company might be organized to manufacture what are essentially copycat devices based on designs that are already on the market. The operators of the company then seek investors in the company, limiting their search to surgeons who can generate referrals that benefit the company. These surgeons are offered “limited partnerships” or similar ownership interests in the company in return for relatively small amounts of money, and can earn returns far higher than the returns they could earn through traditional investment vehicles.

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After the surgeons invest in the company, they are inclined to choose their own company's devices rather than the devices they previously chose on their patients' behalf. However, because it is hospitals or other facilities that purchase the devices to be implanted in patients, physician-owned companies must solicit these facilities for their business. In this way, inappropriate financial incentives spread from the physician-owned company to the facilities with which they do business. Obviously, when a hospital agrees to do business with a company owned by its referring physicians, one of its reasons for doing so is to "keep the physicians happy," i.e., to accede to the physicians' business proposition in order to retain the physicians' stream of referrals.

Surgeons who are passive owners of device companies whose products they implant, and hospitals who do business with such companies, have clear conflicts of interest. These conflicts can only lead to increased costs, reduced innovation, and lower quality. Unlike traditional surgeon collaboration with medical device companies, where the surgeon may actively direct or aid in developing or designing new technologies, the current proliferation of surgeon-owned device companies is often based on distributing passive revenues to a large number of surgeons who have not contributed to development of the product; they simply prescribe its use, and choose to perform the procedures at hospitals that agree to purchase from their companies. This structure means that the surgeons have direct financial incentives to over-utilize their own company's existing devices, and disincentives to funding research and development or to using innovative technologies that may be best for patients.

***The Anti-Kickback Statute.*** Federal laws exist to protect patients from these financial conflicts of interest. The most significant of these laws are the federal Anti-Kickback Statute and the Stark Law (addressed below).<sup>1</sup> The Anti-Kickback Statute makes it a felony for anyone to "knowingly and willfully" solicit, receive, offer or pay "remuneration" in any form to induce, or in return for, referring, selecting, or even just recommending, a particular product payable by a federal healthcare program.<sup>2</sup> Under this statute, it is a federal felony for a hospital to do business with a physician-owned company in return for the physicians' Medicare or Medicaid referrals, or for a device manufacturer to pay a surgeon to select its products for any Medicare or Medicaid patient.

The broad prohibition of the federal statute clearly extends to hospital decisions to do business with physician-owned companies. The government defines prohibited remuneration to include kickbacks, bribes, rebates, or "any other exchanges of value made directly or indirectly, overtly or covertly, in cash or in kind."<sup>3</sup> Moreover, the government has taken a clear stand on its interpretation of the statute. Known in the industry as the "one-purpose" test, the government's position is that even if only one purpose behind the remuneration is to induce referrals, the statute is violated.<sup>4</sup> Thus, even in situations where a hospital purchases devices from a physician-owned company that it would otherwise purchase from an independent company, and even if it pays the physician-owned company less for such products than it would otherwise pay, the hospital would still risk prosecution under the Anti-Kickback Statute because one purpose of delivering business to the physician-owned company is clearly to induce the physicians to refer business to the hospital. Stated conversely, because one purpose of the arrangement is to prevent the physician owners from taking their referrals elsewhere, the hospital is subject to prosecution under the Anti-Kickback statute.

Apart from the physician-owned companies' relationships with hospital customers, however, the relationship between such companies and their physician owners also poses a substantial compliance risk for the physicians. Driven by the Anti-Kickback Statute, the government has long believed and publicly stated that many physician ownership arrangements are suspect because such arrangements may be a method for rewarding physicians for generating referrals. In 1989, the OIG issued a Special Fraud Alert voicing its concern about the proliferation of such problematic joint ventures. The OIG described them as follows:

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<sup>1</sup>42 U.S.C. § 1320a-7b(b); § 1395nn.

<sup>2</sup>*Id.*

<sup>3</sup>See 42 U.S.C. § 1320a-7b(b).

<sup>4</sup>*United States v. Kats*, 871 F.2d 105 (9<sup>th</sup> Cir. 1989); see also *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert denied, 474 U.S. 988 (1985).

Under these suspect joint ventures, physicians may become investors in a newly formed joint venture entity. The investors refer their patients to this new entity, and are paid by the entity in the form of ‘profit distributions.’ These suspect joint 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.<sup>5</sup>

The OIG went on to describe features of such arrangements that are likely to indicate a violation of the Anti-Kickback Statute. The primary feature identified as suspect by the OIG was whether “investors are chosen because they are in a position to make referrals.”<sup>6</sup> Rather than avoiding this highly suspect feature as indicative of an illegal intent, many surgeon-owned device companies instead embrace it as the foundation of their corporate strategy.

***Investment Interests Safe Harbor.*** Because the government interprets the Anti-Kickback Statute so broadly, industry participants asked for clear guidance on types of arrangements involving potential referral sources that are permissible. In response, Congress and the OIG issued statutory and regulatory anti-kickback “safe harbors,” which describe criteria for various arrangements that, if met, protect the arrangements from prosecution. Although failure to comply with a safe harbor’s criteria does not necessarily mean that an arrangement violates the statute, it does mean that it should be scrutinized to determine the intent behind any remuneration that changes hands between the participants. As might be predicted, the typical surgeon-owned device manufacturer arrangement does not comply with the terms of the safe harbor that the OIG has established for investment interests.

One of the requirements of the investment interests safe harbor is that no more than 40% of the ownership of the entity can be held by individuals in a position to make referrals to, generate business for, or furnish services to the entity.<sup>7</sup> By contrast, a typical surgeon-owned device manufacturer may be 100% owned by surgeons and the company’s own managers. In other words, all or virtually all of the investors in such companies are typically “tainted.”

Another requirement of the safe harbor is that no more than 40% of an entity’s gross revenue can come from referrals or business otherwise generated from investors.<sup>8</sup> By contrast, many surgeon-owned device companies depend on investor referrals for virtually all of their business, and would not be able to survive if they prohibited such referrals and relied solely on quality, price, or other legitimate factors to promote their products.

The most significant requirements of the safe harbor, however, and the requirements that provide the most insight into the purpose of an investment interest, concern the terms upon which investments interests are offered to potential referral sources. The safe harbor requires that investment terms offered to potential referral sources be no different from investment terms offered to other investors, and that investment terms not be based on the expected volume or value of referrals from an investor.<sup>9</sup> The typical surgeon-owned device company not only ignores these requirements, but acts directly contrary to their purpose by offering investment terms only to individuals who are surgeons in a position to generate referrals for the company. In these circumstances, the entity’s investment terms are based completely on whether the investor is in a position to refer business to the company. In short, rather than attempting to comply with the government’s safe harbor for ownership interests, these companies act directly contrary to the criteria of the safe harbor, and as a result, run a significant risk of prosecution.

Under the Anti-Kickback Statute, therefore, when a physician-owned device company operates with the purposes of rewarding physicians financially for referrals to the company, and inducing business from hospitals

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<sup>5</sup>Office of the Inspector General, Special Fraud Alert: Joint Venture Arrangements (Aug. 1989), *reprinted in* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

<sup>6</sup>*Id.*

<sup>7</sup>42 C.F.R. § 1001.952(a)(2).

<sup>8</sup>*Id.*

<sup>9</sup>*Id.*

and other facilities by controlling physician referrals to these entities, such a company is pursuing a business plan that violates federal law.

**The Stark Law.** Physician ownership of medical device companies also implicates the federal ban on physician self-referrals, known as the Stark Law.<sup>10</sup> In the 1990s, increasing concerns about physician conflicts of interest led to the enactment of this law, which prohibits physicians from referring certain types of “designated health services” payable by Medicare or Medicaid to entities in which they have an investment interest or with which they have another financial relationship. The purpose of the Stark Law is to create a bright line, “strict liability,” prohibition against physicians having financial relationships with the health care facilities to which they refer Medicare or Medicaid patients. Therefore, regardless of the intent of the parties, if a referral does not comply with the Stark Law, any designated health services performed pursuant to that referral are not payable by Medicare, and any Medicare payments that are received as a result of a prohibited referral constitute overpayments. In this way, a referral that violates the Stark Law results in an overpayment that potentially violates the False Claims Act, potentially resulting in whistleblower lawsuits, treble damages, substantial per-claim penalties, and even exclusion from the Medicare and Medicaid programs.

With regard to physician-owned device companies, the risk of violating the Stark Law is greater than many physicians and hospitals appear to believe. For example, some physicians apparently have a misconception that implantable devices do not fall within the definition of “designated health services” to which the Stark Law applies. On the contrary, however, CMS has clearly indicated that medical devices implanted as part of inpatient or outpatient hospital services do in fact constitute designated health services under the Stark Law.<sup>11</sup>

Some hospitals and physicians also apparently believe that their relationships with hospitals qualify for exceptions under the Stark Law applicable to direct or indirect compensation arrangements. It is unlikely, however, that these exceptions are being met. If a hospital agrees to do business with a company only because it is owned by referring physicians, the prices it pays, regardless of their level, cannot truly be seen as fair market value, in that the hospital would not purchase the devices at any price but for the physicians’ referrals. In addition, both compensation exceptions require compliance with the Anti-Kickback Statute. As discussed above, the typical relationship between a hospital and a physician-owned device does not appear to meet this test.

**Conclusion.** It appears that many device companies and physicians are creating formal business arrangements that can only be viewed as elaborate ways to funnel money to physicians for choosing particular products. Paying surgeons to select particular products violates federal law and the laws of most states, whether the payments are cash slipped under the table or dividends issued to surgeon shareholders. For this reason, the government has repeatedly warned that these types of arrangements are usually illegal. Nonetheless, companies and surgeons continue to pursue them. The physicians, hospitals, and other facilities involved in such arrangements, and the professionals who advise them, should recognize the near impossibility of divorcing the referral motives inherent in these investment offerings from the business relationships among these companies, their hospital customers, and their physician owners, and the resulting likelihood that they are violating federal law.

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<sup>10</sup>42 U.S.C. § 1395nn.

<sup>11</sup>See 66 Fed. Reg. 856, 934 (Jan. 4, 2001).