

Legal Issues for Physician Owned Implant Manufacturer/Distribution Companies (PODs)

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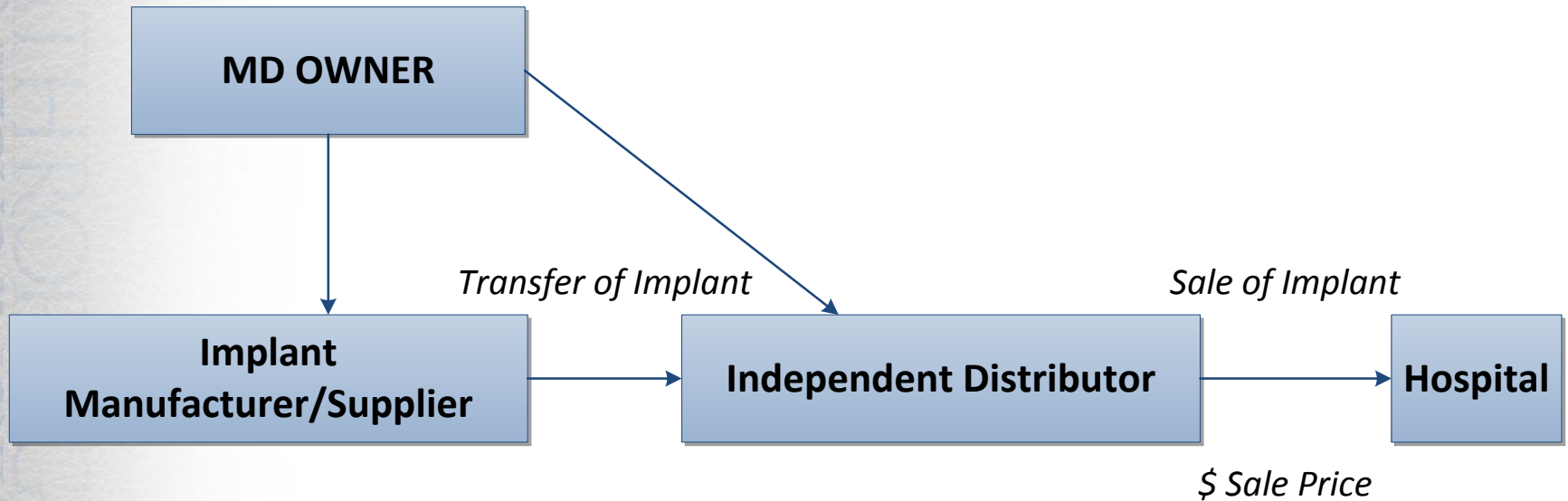
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Typical business structures involve ownership by one or more physicians (collectively the “Physician”) of a company (“Manufacturer/ Supplier”) that would manufacture and/or sell (distribute) implants (the “Implants”) to ambulatory surgery centers or hospitals (“Hospital”).

It is presumed that Physicians will use the Implants on their own patients when performing surgeries in at least one or more of the Hospitals that purchase the Implants. Although there is no direct safe harbor or exemption from Anti-kickback or Stark, arrangements can satisfy federal regulatory requirements if structured as described herein.

The Distribution Arrangement



- The Manufacturer/Supplier should purchase (obtain title) to all assets acquired.
- Carry an inventory of product for supplying sales agents.
- No physician owner of Manufacturer/Distributor should receive any payments in the form of commissions.
- Each owner should make a significant investment in the company.
- The return to all owners should be based upon equity held.

As a Manufacturer/Distributor, the company (and its investors) are required to make large financial investments in manufactured or purchased implants and are subject to substantial financial risks if the implants cannot be sold. All owners should be actively involved in management and product development decisions for the Company and no inducements are made of any kind for the referral by physicians of the Manufacturer/Supplier company products.

Anti-Kickback Statute

The Anti-Kickback Statute (42 U.S.C. § 1320a-7b) is a broadly-phrased criminal and civil statute that prohibits the payment or receipt (or offering or solicitation) of any remuneration, in any form, if such remuneration is intended to induce or reward the referral, recommendation, or arrangement for the provision of any good or service that is reimbursable, in whole or in part, by the Medicare or Medicaid programs (or certain other federal health care programs). Violations of the Anti-Kickback Statute typically arise in “payment for referral” schemes, whereby it is the intent of a party to “reward” referrals of patients

The Anti-Kickback Statute is an intent based statute; that is, the law is not violated unless at least one party to a transaction gave or received remuneration with the intent to induce or reward a referral of federal health care program-reimbursable goods or services. A violation of the law occurs even if ***just one purpose of*** a party to a transaction is to pay for or induce referrals.

If a business arrangement complies with each provision of an applicable “safe harbor”, then that arrangement is “safe.” However, an otherwise commercially reasonable, non-offensive transaction that does not satisfy all elements of a safe harbor is not necessarily illegal and should not necessarily be equated with a violation of the Anti-Kickback Statute.

Potential penalties for violating the Anti-Kickback Statute include substantial fines, imprisonment, and exclusion from participation in the Medicare and Medicaid programs. Any person who violates the statute by either giving or receiving a prohibited kickback, or attempting to do the same, may be punished by as much as five years imprisonment and/or a fine of up to \$25,000. See 42 U.S.C. §1320a-7b(b). Furthermore, 42 U.S.C. §1320a-7a(a) provides for civil monetary penalties of up to \$50,000 per act and treble the amount of remuneration involved for violations of the Anti-Kickback Statute.

Analysis of the Manufacturer/Supplier (“M/S”) Arrangement under the Anti-Kickback Statute is required if a Physician who has an ownership interest in the M/S Company is in a position to refer patients to the Hospital, and if the Hospital would be paying the M/S Company for Implants. The concern is that payment from the Hospital to the M/S Company (which is owned, in part, by Physician) could be viewed as illegal payment in return for referrals.

There is currently no Anti-Kickback Statute safe harbor applicable to the sale of Implants from the M/S Company to the Hospital. Regulators could challenge the purchase price charged by the M/S Company to the Hospital, which likely reflects a profit mark-up, as being in excess of fair market value if the Hospital would be able to directly purchase the Implants from another manufacturer at a lower price (e.g., without the M/S Company's mark-up).

No commission should be paid to any physicians under this relationship. Commissions are deemed to directly relate to the volume or value of referrals and will go directly to the issue of fair market value. It is possible that non-physician, non-owner salesmen could be paid on a commission basis.

Some physicians rely on the 40% small business investment safe harbor found at 42 C.F.R. 1001.952(a)(2). The key elements of that safe harbor state that no more than 40% of the value of the investment interests of each class of investment may be held in the previous fiscal year or previous twelve month period by “investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity”. Thus, the 40% investor limitation is broader than simply physicians who are in a position to refer business. It also includes influencing referrals or furnishing items or services. The concern is that because the non-physician owners are also in a position to furnish items or services to or otherwise generate business for the entity, the 40% investment safe harbor is, by definition, also exceeded.

Moreover, *and most importantly*, the OIG has historically scrutinized arrangements involving health care providers and implants, and has communicated that fraud involving implant and other medical device manufacturing, distribution, and purchasing companies is an enforcement priority. CMS has further questioned the added value of physician involvement in distribution and purchasing companies (noted by CMS as being “essentially middlemen companies”):

“When physicians profit from the referrals they make to hospitals through physician-owned implant and medical device companies . . . [CMS is] concerned about possible program or patient abuse. [CMS’s] understanding . . . is that many [of these companies] are not manufacturers, but rather are companies that profit from the purchase and resale of products made by another organization (that is, they act as distributors) In many cases, the physician investors bear little, if any, economic risk.”

Thus, even absent any illegal intent of the parties, it is clear that the pronouncements of the OIG and CMS discourage physician involvement in distribution arrangements.

If the M/S Company is able to provide Implants at a discounted price, which is then passed onto the Hospital, or if the Hospital has had difficulty obtaining the Implants from other manufacturers or other distributors for some reason, or if the combination of design, product knowledge, service and price can legitimately be shown to be of more benefit to a Hospital than what is available from other suppliers, the transaction is more likely to withstand regulatory challenge. Further, if Physicians are not in a position to directly or indirectly refer products to a hospital (the hospital is located in another state, the Physician does not have privileges at the hospital, etc.), if the M/S Company has a non-physician based distribution system in place, or if it acquires the business of historically unrelated companies for purposes of facilitating its business model, the regulatory situation is stronger.

It is critical that any M/S Company be set up to actively engage, in good faith, in the trade or business of being a medical Manufacturer/Supplier company. If the Physicians are simply standing in a cash flow stream between existing distribution companies and/or manufacturers and a Hospital, the OIG will conclude that the arrangement violates the Anti-Kickback Statute. If a Physician does absolutely nothing for the M/S Company and sits back and takes an investment interest and takes the distribution of profits, the OIG and CMS can also argue that the Physician is simply being paid for referrals.

The Stark Law

In general, the Stark Law prohibits a physician from making a referral to an entity for the furnishing of certain designated health services (“DHS”) to a patient if the physician (or a member of the physician’s immediate family) has a financial relationship with the entity furnishing the DHS, unless an exception applies. The Stark Law prohibits both the physician from making a DHS referral to the entity and the entity from submitting a claim pursuant to the prohibited DHS referral to Medicare.

DHS include, but are not limited to, inpatient and outpatient hospital services, clinical laboratory services, and radiology services.

If the Stark Law applies to an arrangement between a referring physician and an entity (which can include a hospital, or strangely enough the referring physician's own practice), and the arrangement fails to meet a Stark Law exception, then the physician is prohibited from referring DHS to the entity and the entity is prohibited from submitting claims to Medicare for any services that may have been performed pursuant to the prohibited referral.

The Stark Law

In terms of Physician ownership in the M/S Company, if the Physician refers any DHS to the Hospital, the chain of financial relationships between the Physician, the M/S Company and the Hospital (which is the DHS entity) must be analyzed to determine if there is an “indirect compensation arrangement.” Notably, the M/S Company is not a DHS entity under the Stark Law. See 73 Fed. Reg. 48434, 48727 (Aug. 19, 2008).

CMS has specifically addressed this issue, explaining that it is “not adopting the position that physician owned implant or other medical device companies necessarily ‘perform the DHS’ and are therefore an ‘entity’ under the Stark Law, but that CMS “may decide to issue proposed rulemaking on [the physician owned implant or other medical device companies as a Stark Law entity] issue in the future.

The M/S Company is not a “physician organization” under the Stark Law and, consequently, the Physicians would not be deemed to “stand in the shoes” of the M/S Company such that the financial relationship between the Hospital and the M/S Company would create a “direct” compensation arrangement, requiring that the arrangement meet a Stark Law exception applicable to direct compensation arrangements.

However, a Stark Law indirect compensation arrangement exists because (i) there is an unbroken chain of financial relationships between the referring physician and the entity furnishing the DHS; (ii) the referring physician receives *aggregate* compensation from the entity with which the physician has a direct financial relationship that varies with or takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and (iii) the entity furnishing DHS has actual knowledge of the arrangement.

The primary focus of the Indirect Compensation Arrangements exception is whether the per unit compensation paid by the Hospital to the M/S Company for the Implants is fair market value. If the Hospital's purchase price for the Implants is documented to be fair market value, the Physician's ownership in the M/S Company will not prohibit the Physician from referring DHS to the Hospital because the financial arrangement is protected by the Indirect Compensation Arrangements exception. However, concerns about the fair market value of the M/S Arrangement, as discussed above with regard to the Anti-Kickback Statute, are reiterated.

Special Fraud Alert

On March 26, 2013, the Office of Inspector General issued a “Special Fraud Alert” for physician owned entities that focused upon physician owned distributorships (“PODs”). The Alert focused both upon the manufacture of implants and the distribution of implants. Although this special Fraud Alert provided no new insights beyond what was already known before the date of the Alert, it demonstrates that physician owned entities are under very high level of scrutiny and that anyone involved with these types of organizations must be very careful to comply with both state and federal law.

Sunshine Law

Additional regulatory considerations requires disclosure by certain sellers of implants.

Conclusion

There is nothing automatically illegal about a Physician owning a Manufacturer/Supplier company through which a product is being sold to a Hospital or to third party distributors or a Physician owning a M/S Company through which a product is being sold to a Hospital at which the Physician performs patient services using the M/S Company's product. It is critical, however, that any transactions between any of the parties be conducted at fair market value and that all transactions involving the transfer of funds are documented either through a return on investment distribution as defined in an Operating Agreement or through a contract creating a fair market value compensation arrangement.

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