

SUBSTANCE OVER FORM; THE OIG AND CONTRACTUAL JOINT VENTURES INVOLVING PHYSICIANS

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The Office of Inspector General (“OIG”) recently issued an Advisory Opinion that is likely to have a significant impact on many physicians’ business and compensation arrangements. In Advisory Opinion 04-17 (posted 12/17/04) (“AO 04-17”), the OIG focused on a contractual joint venture involving physicians and parties to which they otherwise may refer patients. This Advisory Opinion illustrates a theme that should be critical to parties involved in any business arrangement that may be scrutinized by the federal or state agencies responsible for regulating the health care industry: the parties’ intentions, rather than the structure of their arrangement, ultimately determines whether it will be viewed as complying with the Federal health care programs’ anti-kickback statute. Stated another way, from the government’s perspective, it is the substance of a joint venture, not its form, that determines whether the anti-kickback statute has been violated. The remainder of this article discusses the proposed arrangement and the OIG’s analysis of the contractual joint venture that is the subject of AO 04-17.

Proposed Arrangement

In this Advisory Opinion the OIG was asked to review an arrangement in which the Requestor¹ proposed to operate five pathology laboratories for five different physician group practices (the “Physician Groups”) that specialized in

¹ That is, the party who asked the OIG for this Advisory Opinion. For purposes of clarity, this article uses the capitalized terms employed in AO 04-17.

urology, gastroenterology, and/or dermatology (the “Path Labs”). The Requestor’s plan was to establish and manage all of these the Path Labs in a single building. Each Path Lab would occupy its own space, which would be distinct and separate from the other Path Labs’ space. Each Path Lab also would retain full-time possession of its space and lab equipment. In order to staff its Path Lab, each Physician Group would lease a Pathologist and technical staff from a particular staff leasing company.

Both the Requestor and this staff leasing company were wholly-owned subsidiaries of a common parent entity. In addition, this parent was the sole owner of a Medicare certified anatomic pathology laboratory (the “Affiliated Lab”). Prior the development of this proposal, the Physician Groups referred anatomical pathology specimens to the Affiliated Lab and were expected to continue doing so after the proposed venture became operational.

The Requestor planned to enter into four contracts with each Physician Group: (i) a Management Agreement, which would include equipment leasing provisions, as well as provide an option to provide billing services; (ii) a Pathology Services Agreement for the part-time services of a pathologist retained by the Affiliated Lab; (iii) a Technical Personnel Agreement; and (iv) a Sub-Lease Agreement. The Requestor represented to the OIG that, with the exception of the cost of the supplies, these contractual arrangements would be structured to satisfy all of the standards of the relevant anti-kickback statute safe harbors (specifically, the safe harbors for equipment and space leases, and independent contractors/management services agreements).

Notwithstanding the manner in which these contractual joint ventures were structured, the OIG concluded that they “could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General could potentially impose administrative sanctions Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent,” which was beyond the scope of the OIG’s Advisory Opinion process.²

The OIG’s Analysis

In its 1989 *Special Fraud Alert on Joint Venture Arrangements*, as well as its 2003 *Contractual Joint Ventures Special Advisory Opinion*, the OIG expressed concern about joint venture relationships involving physicians and the businesses to which they refer patients and business. The Special Advisory Opinion identified a number of elements that are characteristic of those physician contractual joint ventures the OIG views as problematic, including: (i) one provider (the “Promoter”) expanding into another line of business by contracting with an existing provider of that business (the “Manager”) in order to provide the new item or service to the Promoter’s existing patients; and (ii) in addition to providing management services, the Manager also supplies the inventory, space, equipment, personnel, billing and other items and services necessary for the Promoter to provide the new item or service. The OIG summarized the elements that are common these relationships as involving a Promoter who “contracts out substantially the entire operation of the related line of business to the [Manager]

² The Centers for Medicare and Medicaid Services (“CMS”) is charged with responsibility for issuing Advisory Opinions related to Stark Law compliance.

– otherwise a potential competitor – receiving in return the profits of the business as remuneration for its federal program referrals.”

Before analyzing the proposed arrangement in light of this Special Advisory Opinion the OIG dispatched with the Requestor’s assertion that because it was a management company, not a health care provider, Requestor was not in a position to engage in activities prohibited under the anti-kickback statute. From this agency’s perspective, it was not necessary for a party to be a health care provider in order to violate the anti-kickback statute. Moreover, because of its close relationship with the other affiliated entities, including the Affiliated Lab (they shared a common interest in all of the entities’ success), the OIG collapsed their relationships and viewed all of them as a single entity for purposes of its analysis. Thus, it was the practical economic relationship these parties had to each other, rather than the legal formalities of their relationships, that the OIG viewed as determining whether the Requestor could be in a position to violate the anti-kickback statute.

Turning to the Special Advisory Opinion, the OIG viewed the Promoter and the Physician Groups as proposing a relationship that would be analogous to the Promoter and Manager discussed above. In this instance, the Physician Groups were doing nothing other than expanding into a related line of business, providing pathology services, the success of which would be dependant on their referrals. The Physician Groups would not participate in the day-to-day management of their Path Labs, but would delegate that responsibility to the Promoter. Moreover, the Physician Groups would not provide any significant

financial, capital or human investment in their Path Labs and, thus, would have little if any real business risk. Indeed, notwithstanding the Requestor's assertion that the Physician Groups would bear a significant financial risk due to their obligations to make payments under the various leases, the OIG concluded that each Physician Group's "actual financial risk would be nonexistent or minimal because it would have complete control over the amount of business it would send to [its] Path Lab and could make substantial referrals to its Path Lab."

The OIG concluded its analysis by stating: "we cannot exclude the possibility that the parties' contractual relationship is designed to permit the Requestor to do indirectly what it cannot do directly; that is, pay the Physician Physician Groups a share of the profits from their laboratory referrals.... By agreeing effectively to provide services it could otherwise provide in its own right for less than the available reimbursement, the Requestor could potentially be providing a referral source – a Physician Physician Group – with the opportunity to generate a fee and a profit."

The OIG then went out of its way to emphasize this agency's long held position that it will disregard the form of an arrangement that appears to fall within a Safe Harbor, if that form is being used for the purpose of masking an abusive or otherwise prohibited arrangement. "[E]ven if each of the individual agreements ... could satisfy the applicable safe harbor conditions ..., the safe harbors only protect the remuneration paid by the Physician Groups to the Requestor for actual services rendered or equipment rented.... [A] Physician

Group's retained profit from the pathology services **would not be protected** by any safe harbor" (emphasis added).

The OIG also responded to the Requestor's argument that this proposed relationship satisfied the requirements of the Stark Law's "in-office ancillary services" exception, and therefore it did not violate the anti-kickback statute. Even if the Requestor's analysis of its compliance with the Stark Law was correct, the OIG stated that would not affect its analysis under the anti-kickback statute "[A]ctual or attempted compliance with the Stark Law is not determinative of whether one intends" to violate the anti-kickback statute. Rather, each is a separate legal authority and must be complied with on its own terms.

Lessons

AO 04-17 does not represent a departure from the OIG's prior positions. Rather it provides a vivid illustration of some of the guideposts that should be observed for parties, particularly physicians, who are involved in contractual joint venture relationships. These guidposts include:

1. It is the substance (that is, the parties' intent), not the form of the arrangement that counts.
2. Parties cannot engage indirectly in payment arrangements that would be prohibited if done directly.
3. Substantial business risk remains an important component in developing arrangements that comply with the anti-kickback statute.

4. The OIG is concerned with the potential of physician contractual joint ventures to violate the anti-kickback statute and is committed to preventing/prosecuting these arrangements.

About the author: Stephen H. Siegel, Esq. has been designated by The Florida Bar as a Board Certified Health Law Attorney. Mr. Siegel's practice focuses on assisting clients who are involved in the health care and pharmaceutical industries doing business throughout the State of Florida. He is a shareholder in Ruden, McClosky, Smith, Schuster & Russell, P.A., general practice law firm, resident in its Miami office, and currently chairs the firm's state-wide Health Law Practice Physician Group.