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Two HHS Warnings Highlight Anti-Kickback Risks For Physicians

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ROBERT THRELKELD

ELLIOTT COWARD

The U.S. Department of Health and Human Services' Office of Inspector General has issued two strong reminders in separate advisory opinions to physicians this past August and September that it does not approve of contractual joint ventures or other revenue-maximizing physician arrangements, and that such arrangements between physicians and various service providers risk running afoul of the Anti-Kickback Statute. The OIG has long been suspicious of contractual joint ventures. In a 2003 special advisory bulletin, the OIG described these ventures as

> Contractual arrangements where a health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier — otherwise a potential competitor — receiving in return the profits of the business as remuneration for its federal program referrals.[1]

Such ventures have appeared in many different types of health services over the years, such as physician-owned pharmacies,[2] pathology,[3] physician-owned medical device suppliers, and of recent note, physician-owned intra operative neuromonitoring companies.

In a 2003 special fraud alert, the OIG identified several suspect factors that should be evaluated to determine whether a contractual arrangement is a prohibited contractual joint venture:

- The owner of the company is seeking to expand into a new line of business that can be provided for the owner's existing patients.
- The new line of business predominantly or exclusively serves the owner's existing patient base: a captive referral base.
- The owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the manager or supplier, while retaining profits generated from its captive referral base — in other words, there is little or no bona fide risk.
- The manager or supplier is a would-be competitor of the owner's new line of business and would normally compete for the captive referrals.

- The manager or supplier provides all or many of the key day-to-day operational services, such as management, billing, equipment, personnel, space, training and inventory.

- The practical effect of the arrangement, viewed in its entirety, is to provide the owner with the opportunity to do indirectly what it cannot do directly; that is, receive a share of the profits from its referrals. The remuneration from the venture to the owner, i.e., the profits of the venture, takes into account the value and volume of business the owner generates.

- The arrangement may involve exclusivity.

When OIG is seeking to remind health care providers that it takes its positions seriously, it often issues multiple advisory opinions on similar topics but explores different agreements. That is precisely what happened in August and September when the OIG issued Advisory Opinions 23-05 and 23-06, each addressing prohibited contractual joint ventures or other revenue-maximizing arrangements between physicians and service providers.

In Advisory Opinion 23-05, the HHS OIG has **called into question** a spate of intraoperative neuromonitoring, or IONM, arrangements.[4]

IONM is a service in which a patient's neural pathways are monitored during neurosurgery. There is both a technical portion of the service involving placing the equipment in the operating room and a professional portion involving the actual monitoring and interpretive services.

Historically, these services have been performed by specialized IONM companies and neurology practices. More recently, numerous arrangements have arisen that would allow physicians to own and bill for some or all of the IONM services and to contract with a management company that does tasks like managing billing and contracting with the remote neurologist.

The management company receives a management or administrative fee, while the physician owners receive the remainder of the professional and technical fee, depending on the arrangement.

In Advisory Opinion 23-05, the requester was an IONM company that had historically performed and billed for the full slate of IONM services but more recently had considered entering into these management arrangements with physicians hoping to set up their own billing companies.

The requester represented to OIG that it was being pressured to do this because otherwise its physician clients would leave and go elsewhere to other companies that would manage their services.[5]

In this case, the OIG issued a negative advisory opinion. It found that

> The Proposed Arrangement would implicate the Federal anti-kickback statute. It would involve several forms of remuneration, including, but not limited to: (i) discounts under the Personal Services Agreement provided by Practice to Newco; (ii) the opportunity for Newco to generate a profit through the difference between the fees paid by Newco to each of Requestor and Practice under the services agreements and the reimbursement Newco would receive for such services from third parties; and (iii) returns on investment interests in Newco to the Surgeon Owners. These streams of remuneration could induce the Surgeon Owners to make referrals of IONM services for which payment could be made by a Federal health care program. The arrangement presented a high risk of fraud and abuse.

The OIG then noted that there is no Anti-Kickback Statute safe harbor that would protect the arrangement. It then noted that there is a significant risk of fraud and abuse under the arrangement. When analyzing contractual joint ventures, the OIG often uses the same buzzwords:

> The Proposed Arrangement could enable Requestor and Practice to do indirectly what they could not do directly: pay the Surgeon Owners a share of the profits from their referrals for IONM services that could be reimbursable by a Federal health care program.

The OIG found here that the described IONM arrangement exhibited many concerns identified in its special fraud alert on contractual joint ventures. As a result, the OIG stated that the venture would likely generally prohibit remuneration under the Anti-Kickback Statute.

Advisory Opinion 23-06 **involved** a requester who operated anatomic pathology laboratories across the country and who also seemed to be specifically seeking a negative advisory opinion.[6] The requester explained that lab remuneration typically involves payers reimbursing the requester for two components: the technical component, which covers the physical preparation of the specimen, and the professional component, which covers the analysis by a pathologist.

The requester stated that it had been approached by various laboratories that propose to enter into arrangements with the requester that would require the requester to purchase the technical component of anatomic pathology services from the other laboratory, which may in many cases be owned by physicians, for certain anatomic pathology tests for commercially insured patients.

Specifically, (1) the physician laboratory or nonphysician laboratory would perform the technical component of the referred sample; (2) the requester then would perform the professional component and would bill commercial insurers as an in-network provider for both the technical and professional components; and (3) the requester would pay the referring laboratory a fair market value per specimen fee for preparing the technical component.

The requester further stated that, although some of the laboratories may have the capability to perform both the professional and technical components themselves, they wish to enter into the proposed arrangement because they are unable to bill certain commercial payers for anatomic pathology services.

The requester also certified that, although the fee it would pay to laboratories under the arrangement would be fair market value for technical component services, the requester has the capability to perform both components itself, which is generally both more efficient and more cost-effective than paying a third-party laboratory to perform the technical component.

Without implementation of the proposed arrangement, the requester itself would have the opportunity to perform, bill for and retain the full reimbursement for anatomic pathology services billable to commercial payers, rather than sharing a portion of the work — and the reimbursement — with a third-party laboratory.

Although the third-party laboratories would not be required to refer any federal health care program business to the requester, the proposed arrangement would likely result in referrals of federal health care program business to the requester from third-party laboratories. Conversely, the requester predicted that if it did not enter into the proposed arrangement, it would likely not receive a significant volume of referrals.

In issuing its opinion, the OIG explained that the arrangement would likely result in prohibited remuneration explaining that

> (i) in most instances, it is already capable of performing both components of anatomic pathology services without referring the technical component to a third-party lab; (ii) performing both components in-house is generally more efficient and cost-effective than paying a third-party lab; and (iii) at present, Referring Physicians are more likely to refer anatomic pathology services to laboratories that have contracts with commercial payors, like Requestor. It is difficult to discern any commercially reasonable business purpose for Requestor to enter into the Proposed Arrangement — forgoing the opportunity to bill and retain payment

for both components of the anatomic pathology services, in an arrangement that is both less efficient and more costly — other than the possibility that such payment may induce referrals of patients, including Federal health care program beneficiaries.

The OIG also included its perennial warning that a carveout of federal health care patients is insufficient to protect an arrangement.

The arrangements in these two advisory opinions are different, as is the OIG's rationale. But both arrangements should remind health care providers, including physicians, that arrangements with service providers that are purely designed to maximize revenue — not to achieve a bona fide care-related purpose that couldn't otherwise be achieved — should be viewed with caution.

These opinions also should remind physicians that any arrangement that has the effect of holding a traditional service provider hostage in order to allow the physicians to obtain revenue at the expense of the traditional service provider in exchange for continued referrals, will be viewed negatively.

Robert Threlkeld and Elliott Coward are partners at Morris Manning & Martin LLP.

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[1] https://oig.hhs.gov/documents/special-advisory-bulletins/885/042303SABJointVentures.pdf.

[2] https://oig.hhs.gov/documents/advisory-opinions/391/AO-98-16.html; https://oig.hhs.gov/documents/advisory-opinions/616/AO-11-03.pdf.

[3] https://oig.hhs.gov/documents/advisory-opinions/489/AO-04-17.pdf; https://oig.hhs.gov/documents/advisory-opinions/661/AO-13-03.pdf.

[4] https://oig.hhs.gov/documents/advisory-opinions/1128/AO-23-05.pdf.

[5] This request was interesting because the requester seemed, in many ways, to be seeking a negative opinion. For example, the requester stated that it only entered into such arrangements when the physicians were otherwise threatening to stop using Requestor for IONM services. It further represented that "as a practical matter" it would not be able to enforce a federal patient carve-out. As the main service provider of IONM, the requester clearly was more profitable before physicians started pressuring it to allow them to participate in the IONM profits. The requester may have been seeking to chill such arrangements.

[6] https://oig.hhs.gov/documents/advisory-opinions/1131/AO-23-06.pdf.