HHS OIG Identifies Potential Violation of Anti-Kickback Laws In Proposed "Block Lease" Arrangements Between Physician Groups

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On August 26, 2008, the Office of Inspector General of the Department of Health and Human Services ("OIG") issued an Advisory Opinion [click to download PDF] to a physician group practice, finding potential anti-kickback violations with the group's proposal to "block lease" space, equipment, and personnel to other referring physician groups. The Advisory Opinion continues the OIG's historical concern with joint venture arrangements involving parties with existing or potential referral relationships, as well as highlighting its concern regarding "block lease" arrangements. In this case, the particular clinical specialties involved happened to be urologists and a radiology/radiation therapy group - a combination concerning which CMS has also recently expressed Stark-based concerns. However, the questionable components of the proposed arrangement reflected in the OIG's analysis are equally applicable to other similarly situated physician groups with referral relationships.

Proposed Arrangement
Under the proposal reviewed by the OIG, a physician group practice (the "Requestor"), specializing in radiation and chemotherapy treatment, proposed entering into lease agreements with several urologist groups ("Urologist Groups") through which the Urologist Groups would provide intensity-modulated radiation therapy ("IMRT") services in the Requestors' free standing cancer treatment facility. The agreements would involve renewable one year, fixed priced contracts, permitting the Urologist Groups to lease examination and treatment rooms, equipment, supplies, and personnel from Requestor. The Urologist Groups would also compensate Requestor for communication and administrative expenses. Under the proposed arrangement, radiologists associated with the Requestor would act as independent contractors to the Urologist Groups and would supervise the IMRT procedures. It is important to note that IMRT is currently performed in the treatment facility by the Requestor, and the Urologist Groups currently refer prostate cancer patients to receive IMRT to the Requestor. The Requestor would continue providing IMRT services. In contrast, none of the Urologist Groups currently provide IMRT services.

The Requestor would bill Medicare for the professional and technical components of IMRT services, but the claims would be submitted under billing numbers assigned to the respective Urologist Groups for "their" services. In turn, the Urologist Groups would pay the Requestor amounts owed under the lease agreements, thereafter retaining the difference between the fees collected for "their" IMRT services and the amounts owed to the Requestor under the lease agreements.

OIG Analysis
The OIG concluded, based on the information provided by the Requestor, that the proposed arrangements could potentially involve prohibited remuneration under anti-kickback laws and could also warrant administrative sanctions. The OIG found the proposed arrangements included provisions that resembled suspect and problematic "contractual joint venture" arrangements. The OIG specifically expressed strong concern that the proposed arrangements would indirectly permit the Requestor to provide the Urologist Groups with an opportunity to provide services to generate a profit.
The Advisory Opinion recounts OIG's longstanding concern regarding joint ventures involving current or potential referral sources. These concerns were first noted by the OIG in its Special Advisory Bulletin on Contractual Joint Ventures (68 Fed Reg. 23148, April 30, 2003). Based on that framework of concerns, the OIG examined the proposed arrangement and identified factors present in them consistent with "problematic" joint venture arrangements. Those factors included the facts that: 1) the Urologist Groups would expand into a related line of business with minimal financial or business risk; 2) the Requestor and Urologist Groups would both provide IMRT services that the Requestor is currently providing itself and would retain fees derived therefrom; 3) the Urologist Groups would use the premises, equipment and staff of the Requestor to serve patients that were historically referred to the Requestor; 4) both the Urologist Groups' and Requestor's aggregate income would vary according to referrals from the Urologist Groups to the facility; and 5) the Requestor, the radiologists and the Urologist Groups would share in the economic benefit of IMRT services.

Based on these facts, the OIG concluded that the arrangement was designed to permit the Requestor to indirectly offer the Urologist Groups impermissible remuneration. The OIG reasoned that "by agreeing effectively to provide services [the Requestor] could otherwise provide in its own rights for less than the available reimbursement, the Requestor and its Radiologists would potentially be providing a referral source - a Urologist Group - with the opportunity to generate a fee and profit."

The OIG declined to opine on the applicability of any safe harbors under the proposed arrangement, but noted that if a safe harbor did apply, it would "only protect the remuneration paid by the Urologist Groups to the Requestor or to the individual Radiologists for actual services rendered or space or equipment rented."

**Conclusion**

The OIG Advisory Opinion process typically results in the OIG blessing arrangements which the submitter generally anticipates will be acceptable. Indeed, Advisory Opinion requests are often withdrawn if they appear to be heading in the wrong direction. In this proposal, however, the OIG was presented by the Requestor with a combination of business elements it simply does not like: a joint venture between entities involved in a referral relationship, a "block lease" arrangement, and a business model which incentivizes higher rather than lower Medicare utilization. Indeed, given this combination of risk elements in this particular proposal, speculation arises as to whether the Requestor could have reasonably expected that the OIG would view the arrangement benignly. At least as likely, it seems, is the possibility that the Advisory Opinion was sought as a defensive measure to thwart potential competitive activity. In any event, the OIG predictably viewed the confluence of deal elements described above as a volatile anti-kickback mix - even if all Stark-related technicalities could be satisfied.

Physician group practices currently involved in referral relationships will be wise to recognize the risks attendant when contemplating moving toward similar types of "partially integrated" (independent groups with close business alignment) - but not "totally integrated" (single group) - business models.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.