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Health Law Alert

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November 2008

Advisory Opinion No. 08-10: Review of Block Lease Arrangement

In late August, the Office of the Inspector General of the United States Department of Health and Human Services ("OIG") issued Advisory Opinion No. 08-10, which reviewed a block lease arrangement involving urologists using Intensity Modulated Radiation Therapy ("IMRT"). This Opinion reflects continued government antipathy toward shared ancillary services among referring physicians. Similar concerns have driven recent Stark III and related changes, such as the anti-mark-up rule.

At issue in Advisory Opinion No 08-10 was a fairly common structure pursuant to which urology groups would lease from a radiation oncology physician group practice, on a part-time basis, space, equipment, personnel and radiation and other supplies and administrative and billing services needed to perform IMRT. Compensation would be a fixed amount set in advance, that would not vary based on utilization. The agreements are certified to be at fair market value, a one year term, and are in effect assumed in the opinion to have met all other Anti-Kickback Law Safe Harbor requirements.

Noting that even if the agreements making up the proposed arrangement could each satisfy the applicable Anti-Kickback Law Safe Harbor conditions, the OIG wrote that it would only protect the amount paid by the urology groups to the radiation oncology group practice for services rendered or space or equipment leased. The OIG noted, however, that "in this Opinion, we are concerned about potential compensation to the Urologist Groups, who are sources of referral to the [radiation oncology group] for the very services to be provided under the Proposed Arrangement." In the Special Advisory on contractual joint ventures issued in 2003 and the 1989 Special Fraud Alert on joint venture arrangements, the OIG found that a sham relationship is not protected by technical compliance with Safe Harbors. Applying those principles here the OIG reasoned that the retained profit of the urologist group after paying all amounts due to the radiation oncology practice was effectively remuneration. In other words, by agreeing to provide services that they could otherwise provide for less than the available reimbursement, the radiation oncology group's leases of space, equipment and personnel to the referring groups provided the referring groups with an opportunity to generate a fee and a profit. Finding that profit could be a kickback if made with the requisite intent, the OIG stated that "there is a significant risk that the Proposed Arrangement would be an improper contractual joint venture that would be used as a vehicle to reward… referrals."

This Opinion reflects the most aggressive discussion yet by the OIG on "block lease" arrangements. As compared with the 1989 and 2003 advisories, there is substantially less evidence here that the urologist group would not be the *bona fide* provider of the services. In the other circumstances, the OIG noted that there was no investment of time, money or resources and the involvement of the billing entities was remarkably limited. Here, however, the urology group had to lease the space on a fixed block amount of time. As such, they were at risk in that either they would not have enough work to fill up that time and end up losing money, or they would have more work then they could otherwise use and would have to "leave money on the table," unlike transactions structured on a pay as you go basis, or otherwise without risk. Moreover, radiation oncology services are subject to substantial liabilities, and these would belong to the urology group. The urology group was also responsible for billing and any billing fraud. The amounts paid to the radiation oncology group were of course paid without regard to receipts ultimately obtained by the urology group. Finally, and perhaps most importantly, the care received by the urologists' patients would have been

integrated with one provider, which has legitimate medical advantages. While the OIG may not be happy with the arrangement, it does not appear to be a sham on its face.

Perhaps more significantly, the OIG's analysis does not appear to be limited to situations where space, equipment or personnel are shared. For example, it is generally accepted that a urology group could hire its own radiation oncologist to provide radiation oncologist services on behalf of the group. While the opinion does not address this issue, its rationale would appear to apply equally to this circumstance. The fact is, the radiation oncologist is in the business of getting referrals from the group and now would be providing professional, if not technical services, to the group. Does this violate the law? What if a general practice hires a surgeon. Is the difference between what the surgeon is paid and what the surgery generates now an improper kick-back, such that it would not matter, according to the OIG, if the personal services or employment exceptions were met? Obviously, if this is what the OIG means, the Opinion could force restructuring of the way physician services are rendered in the United States. It is hard to believe such a profound result was intended.

Unfortunately the Opinion does not provide any comfort. It does not suggest that if the contract were a certain percentage of the entire available time for use of the equipment and personnel, it would suffice. It doesn't discuss the degree of integration between the leased facility and the urologist group itself. Remarkably, the OIG is not even impressed if the structure meets the explicit regulatory requirements (the applicable Anti-Kickback Law Safe Harbor and Stark regulatory exception) that have been carefully set through rulemaking, and proposes in effect to overrule them in an informal agency guidance such as this advisory opinion. Nor is there any protection in the Safe Harbors at all, if the OIG can simply ignore them and find that a relationship that fully complies with the Safe Harbor still violates the Anti-Kickback Law.

It is not rational to argue, as the OIG does, that the Safe Harbor only protects the payments to the contracting entity and not the profits retained by the contractor (in this case the urologist group). It would seem that only where the billing by the contracting entity is improper can the differential between the amounts received by it and the otherwise lawful, Safe Harbor-compliant payments made to an entity with which it contracts be held to violate the Anti-Kickback Law. Heretofore, the OIG has generally permitted this structure, finding only where (i) the entity providing the service was in fact the contracting entity (the radiation oncology group herein), and (ii) where the contractor (e.g., the urologist group) was not even involved in the service, and thus had no right to bill, could the difference in what was received from third parties and what is paid to the true service provider be a kickback. Here, however, the structure was carefully designed to make the group the actual provider, with clear responsibilities for services rendered, an active practice independent of the radiation oncology services for at least eight hours a week at the site (as required by the Stark Law), and fixed times for which it leased personnel and equipment and space for an entire year.

No earlier holdings of the OIG have reached so far. It appears to us that the inconsistency with the regulatory structures that are in place, including the Stark exception for in-office ancillary services and the Anti-Kickback Safe Harbor for personal services agreements, suggest that this Opinion should be read narrowly, and applied particularly to circumstances where there is not an adequate integration of the leased service into the leasing group. However, it is not at all clear that the OIG would agree.

Further developments are expected and block lease agreements must be carefully reviewed.

Edward Kornriech 212.969.3395 ekornreich@proskauer.com
Herschel Goldfield 212.969.3977 hgoldfield@proskauer.com