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The OIG Finds Potential F&A Violation

The Office of Inspector General for the U.S. Department of Health & Human Services ("OIG") has found potential illegality in a business arrangement which has been structured so that each element of the arrangement complies both with Stark and with the fraud and abuse provisions of the Social Security Act.¹ In AO 08-10,² the OIG determined that the proposed arrangement could potentially generate prohibited remuneration and that the OIG could potentially impose sanctions on the parties if the arrangement went forward.

Three facts about the proposed arrangement make the analysis in this AO particularly interesting:

- The proposed arrangement was structured to comply with the in-office ancillary services ("IOAS") exception under the Stark Law. Because the OIG did not elaborate or express its opinion on this point, it is unclear whether the arrangement actually meets all of the exception's requirements, but there appears to be no reason to believe it does not comply with the IOAS exception.
- The proposed arrangement was structured so that each and every element of the arrangement complied with one or more applicable anti-kickback safe harbors, which the OIG did not dispute.
- Although the various elements of the proposed arrangement included the lease of space, equipment, and personnel as well as personal services arrangements between two physician groups (which again were structured to comply with the applicable safe harbors), the OIG concluded that the proposed arrangement looked like a contractual joint venture between physicians and a supplier. Therefore, the OIG concluded, the proposed arrangement would be judged like a contractual joint venture and scrutinized accordingly³.

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The arrangement described in the AO is not very different from arrangements currently in effect all around the country.

One physician group ("Group I") owns a cancer treatment facility ("Facility") that provides radiation and chemotherapy treatments, including intensity-modulated radiation therapy ("IMRT"). In an effort to provide needed services to their patients in a cost-effective manner, urologists in the area ("Urologist Groups") would lease the Facility from Group I on a block-time basis (for example, for 4 hours on Tuesday and 6 hours on Friday). The lease would include the lease of space, equipment, and personnel services necessary to perform IMRT.

In addition, each Urologist Group would lease examination and treatment rooms at the Facility for fixed periods of at least eight hours per week in the same space where Group I provides IMRT. That area would be used by the Urologist Group to provide exams and treatment to its patients which are not related to the IMRT therapy the patients may also need. In addition to the space, equipment and personnel, Group I would provide the Urologist Groups with radiation supplies and billing services. Individual radiologists associated with Group I who normally perform services billed by Group I (the "Radiologists") would enter into contracts with the Urologist Groups to supervise the IMRT procedures, as independent contractors for the Urologist Groups.

In exchange for the space, equipment, and services described above, the Urologist Groups would pay Group I rent for the space and equipment and fixed expenses for the personnel and administrative services provided. Compensation under the various arrangements would be for fixed amounts that were set in advance, and the amounts would not vary with the use of the premises, equipment, or services. Group I certified that the compensation under the leases would be set at fair market value based on a fair market value analysis prepared by an independent third party.

The agreements between Group I and the Urologist Groups would each have a one-year term, with an option to renew upon a ninety-day advance written notice. The Urologist Groups must pay Group I under the leases whether or not they refer any patients for IMRT. Members of the Urologist Groups would see patients at least six hours per week in the same building where the IMRT services are provided as well as provide patients with services unrelated to the IMRT

services.

In recent Stark Law rule changes (including those adopted in the 2008 Physician Fee Schedule (“PFS”) rule and those proposed in the 2009 PFS rule), the Centers for Medicare and Medicaid Services (“CMS”) is reviewing the “same building” requirements for compliance with the IOAS exception. The ability to provide services in part-time space is also affected by the express adoption of the Medicare anti-markup requirements into the Stark Law requirements.

Through its recent Stark Law changes and its continued seeking of comments to the use of the IOAS exception, CMS appears to want to draw some limitations on the ability of physicians to provide and bill for services that are provided through lease arrangements with other providers. The concern appears to be focused on the belief that ancillary services must in fact be ancillary to the full-range of services offered by the physician or physician group. It is unclear how the anti-markup changes and any possible changes to the IOAS exception would have affected the proposed arrangement.

With that in mind, it appears that the OIG may have beaten CMS to the punch by focusing not on any of the internal organizational relationships of a physician group ancillary services arrangement, but on the payment made to the physicians—in this case, the Urologist Groups—who submitted the claims for payment from the Medicare program.

If Group I’s assertions are to be believed, and the OIG did not disagree with their assertions, all of the following are true:

- All of the leases provide for fair market value compensation that does not account for the volume or value of any referrals in any direction, provide for terms of at least one year, and provide for block-time lease arrangements.
- The personal services arrangements are with Radiologists who are “associated” with Group I, but appear to be contracts that are independent of any arrangement between the Radiologists and Group I.
- No party shares in revenues as would normally be the case in a standard joint venture arrangement. A straight, block-time lease of space, equipment, and personnel does not create a joint venture. In fact, Group I receives rental payments regardless of use of IMRT by the Urologist Groups and regardless of

whether the Urologist Groups get paid by Medicare, another payor, or the patient.

Despite all this, the OIG decided that the proposed arrangement is fraught with danger of violating the fraud and abuse provisions of the Social Security Act, based on the following observations:

1. On the whole, the Urologist Groups would commit little in the way of financial, capital, or human resources to the IMRT services and, accordingly, would assume very little real business risk.

However, the business risk the Urologist Group does assume is liability for lease payments for ALL of the services, whether or not they are able to use them.

2. The Urologist Groups would be in a position to ensure the success of the business, not only by referring to Group I for IMRT, but by the choice of IMRT over other available therapies for prostate cancer.

The problem with this observation is that this is the case in every single choice a physician makes for his or her patients. It is also an important element of any malpractice claim and would certainly be reviewed by any payor in a medical necessity challenge. Alone, it does not really support a claim of illegality. Any time a physician adds an ancillary service to his or her practice—whether that be a pharmacy, on-site mammography, or an array of lab services—the physician is in a position to ensure the success of that endeavor by making it available to his or her patients. From the patient’s perspective, he or she is often grateful for the convenience of having the ancillary services in the physician’s office as well as the level of control the patient retains by being able to turn to the physician for any issues, including those involving the ancillary services. The patient can take any complaints directly to the physician if something does not meet with their approval. If a physician follows all the rules and regulations required to make those services available as part of his or her practice, how is it that the OIG can use the fact that the services are available to patients as evidence of illegality?

3. "Although not essential to our conclusion, we note that, in negotiating the agreements that make up the Proposed Arrangement, the lease times as well as the amount of space, equipment and staff leased or contracted for could readily be determined based on the historical patterns of referrals by a Urologist Group."

Based on the realities of a physician practice, this observation makes little sense. How else can the Urologist Group determine whether it needs IMRT for its patients than to look at its historical referral pattern? This observation, on its face, requires that one reach the conclusion that the Urologist Group does not intend to increase referrals in exchange for the facility fees, which it may or may not receive depending on all of the other factors that determine whether a payor even pays a claim.

4. "The Requestor [Group I] is an established provider of the same services that a Urologist Group would provide via the Proposed Arrangement and is in a position to directly provide the IMRT in its own right, billing Medicare in its own name, and retaining all available reimbursement. A Urologist Group would use the premises, equipment and staff of the Requestor to serve its own patient base – the very patients some of the Urologist Groups have historically referred to the Requestor or other outside suppliers for the same services."

Assuming that this is all correct, it is unclear whether that is reason enough to conclude that a business arrangement should be found to be illegal.

5. "The aggregate income to the Urologist Groups under the Proposed Arrangement would vary with referrals from the Urologist Groups to the Facility, and, because the various agreements could be tailored to fit the historical pattern of referrals by the Urologist Groups, so might the income to the Requestor."

The income to Group I (who is also the "Requestor") would not vary. The compensation terms of the proposed arrangement sets the rental fees at a fair market value amount for block-times. The aggregate income to the

Urologist Groups will always vary depending on the number of patients it serves. But once again, this does not seem to be a good reason to find the arrangement illegal.

6. "The Requestor (and its individual Radiologists engaged as independent contractors by the Urologist Groups) and the Urologist Groups would share in the economic benefit of the IMRT."

While true, the sharing of an economic benefit of any business arrangement is not, in and of itself, illegal. If each and every element of a safe harbor is met and each and every element of a Stark Law exception is met, the fact that all parties to a transaction profit from the transaction is good business. It is good for the Medicare program, and it is good for health care in this country generally.

¹ I was going to begin this article: "As my Minnesota grandmother used to say, 'Well, if this don't beat all.'"

² Advisory Opinion 08-10 ("AO 08-10") on its website on August 26, 2008 See <http://www.oig.hhs.gov/fraud/advisoryopinions/opinions.html>.

³ See OIG Special Advisory Bulletin: Contractual Joint Ventures (Apr. 23, 2003; www.oig.hhs.gov/fraud/fraudalerts.html).

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