

## How Recent Federal Law Developments Affect Business Models for Collaborative Oncology Care

by Michael L. Blau, Esq.

The federal agencies responsible for regulating financial relationships among oncology providers had a busy year in 2008. In the past year, the Centers for Medicare & Medicaid Services (CMS) issued new Stark Law rules,<sup>1</sup> and the Office of the Inspector General (OIG) issued Advisory Opinion 08-10, which may adversely impact certain collaborative ventures among oncology providers.<sup>2</sup> In 2008, CMS also adopted new anti-mark-up rules and new standards for independent diagnostic testing facilities (IDTFs, which are Medicare-certified imaging facilities) that may also adversely affect certain collaborative arrangements among oncology providers and suppliers.<sup>3</sup> These regulatory changes will affect certain:

- Space and equipment leases
- Block lease and shared diagnostic testing arrangements
- Investment interests in certain turn-key development or management company joint ventures, and so-called “under arrangements” transactions
- Turn-key management service transactions.

The net effect of these recent federal legal developments is to narrow somewhat the options for structuring these business ventures among cancer care providers—whether among oncologists and other physicians or medical groups, or between oncologists and hospitals or other suppliers.

### “Per Click” and Percentage Arrangements

As of Oct. 1, 2009, the new Stark law rules will prohibit oncologists (or their immediate family members) from directly or indirectly being a party to any percentage-based or payment “per click” equipment or space lease with any other provider to which the oncologist refers for “designated health services” (DHS).

Among other services, DHS includes imaging, radiation therapy, laboratory, outpatient pharmaceuticals, and hospital services. Over the last decade, many PET/CT, MRI, IMRT, IGRT, SRS, Gamma Knife, Cyberknife, and other equipment ventures were structured on a percentage of revenue or payment “per click” basis. If these ventures involve referring physicians, they will need to be restructured to fair market, fixed-rate (daily, weekly, monthly, or annual) arrangements before the Oct. 1, 2009 deadline. This change will apply whether the referring physician is (directly or indirectly) the lessor or the lessee of the equipment or space, and regardless of whether the equipment or space lease is based on a percentage of billings, collections, or profits, or is on any type of payment per unit of service basis.

### Shared-Space Arrangements

In addition, a new Stark Phase III rule already in effect prohibits certain shared-space arrangements with a referring physician (or what I call the “next available exam room” arrangement). An example of a “next available exam room” arrangement is one in which a surgical oncologist “rides circuit” and provides services at the offices of several medical oncologists. The medical oncologist owns or holds a lease to office space that includes, for example, ten exam rooms. The medical oncologist subleases one of the exam rooms to the surgical oncologist on a shared-use basis one day per week. Not infrequently, the shared-space arrangement is that the surgeon uses any exam room that is vacant and ready for the next patient. This type of arrangement is now outlawed by the new Stark law space-rental standard that requires a period of *exclusive use of some identified portion of the leased space* by the surgeon lessee if the physicians are to be free to refer to one another for Stark-covered services.

### “Turn Key” Arrangements and the Anti-Kickback Statute

The final Stark Phase III rule affirmed that, in general, block lease arrangements (such as a lease of PET/CT equipment by a radiology group to a medical oncology group or urology group on a day-rate basis) are not forbidden by the Stark law. However, OIG Advisory Opinion 08-10 delivered the message that “turn-key” block lease or “turn-key” management arrangements may be suspect as potentially impermissible “contractual joint ventures” under the federal Anti-Kickback Statute.

In Advisory Opinion 08-10, the OIG disapproved of a proposed series of IMRT block lease and service arrangements between an oncology group and urologists. The oncology group that included radiation oncologists already owned IMRT equipment and employed radiation techs, and used these to provide IMRT services to its own patients. The oncology group proposed to lease its equipment and techs, and to provide support services to the urologists to enable them to provide IMRT services to their own patients one day/week. The proposed contracts were fixed fee, fair market value contracts and appeared to be properly structured to meet applicable equipment and management services safe harbors to the Anti-Kickback Statute and applicable Stark Law exceptions. In other words, on their face, these contracts appeared to be specifically protected arrangements.

Nonetheless, the OIG found that such a turn-key deal between providers may constitute an impermissible contractual joint venture between the oncologists and referring urologists, because:

1. The oncology group itself could have provided the IMRT services to the urology patients
2. Instead, the oncology group gave the urologists the opportunity to



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profit from each IMRT service (to the extent of the spread between the cost of the service charged by the oncology group to the urologists and the Medicare/third-party payment rate for the IMRT services)

3. The OIG viewed this opportunity to profit as potentially “improper remuneration” to induce referrals from the urologists to the oncologists.

The OIG stopped short of saying that the arrangement was necessarily illegal; but indicated that it would be unlawful if any purpose of the arrangement was for the oncologists to obtain or maintain referrals from the urologists.

### “Under Arrangement” Ventures

Effective Oct. 1, 2009, certain forms of “under arrangements” ventures will be prohibited. The types of arrangements affected will be those that involve physician ownership of, for example, a joint venture radiation therapy or infusion facility development or management company that “performs” a Stark-covered service (such as radiation therapy or infusion of Medicare-covered pharmaceuticals).

An “under arrangements” venture is one in which one provider outsources a service to another supplier who performs the service on the first provider’s behalf. For example, a hospital may enter into a joint venture with oncologists to develop a radiation therapy facility or an infusion center. The resulting joint venture entity may develop the facility—it may obtain the space and equipment, develop the leasehold improvements, and hire the staff—and it may also provide support

services to manage the resulting radiation therapy facility or infusion center. This joint venture development and management company may then provide the fully developed facility to the hospital “under arrangements”—that is, on a lease, license, or service contract basis. In other words, this service becomes an outpatient service of the hospital that the hospital can then bill for, under the hospital’s license and providers’ numbers, at hospital outpatient rates.

However, under new Stark law rules that go into effect on Oct. 1, 2009, a physician (or immediate family member) will generally be prohibited from having an investment interest in an entity that “performs” a Stark-covered service (such as radiation therapy or hospital infusion services) to which the investing physician refers.<sup>3</sup>

In the above example, the joint venture development and management company could be viewed as “performing” the technical component of the radiation therapy or infusion service on behalf of the hospital. If the joint venture entity, in fact, “performs” the radiation therapy or infusion service, then, under this new Stark rule, the investor physicians would be prohibited from having any ownership interest in the joint venture.

That said, limited exceptions to this prohibition exist for investment interests that meet the Stark law exception for ownership interests in rural providers or publicly traded securities.<sup>4</sup> Also, if the “under arrangements” service is provided by a single oncology group, and not by a joint venture in which oncologists invest, then the investment interest in the oncologist’s own group may meet the Stark law in-office ancillary services exception.<sup>5</sup>

To complicate matters, in the final Stark rule, CMS expressly declined to provide guidance as to what it means to “perform” the service [i.e., what combination(s) of providing space,

equipment, supplies, non-physician clinicians, administrative staff, and executive services constitutes “performing” the service]. Based on our discussions with CMS, we believe that a joint venture entity should not be viewed as performing the service if it does not provide any part of the clinical component of the service (such as physician, technologist/technician, nurse, and/or mid-level practitioner services).

Accordingly, it appears that there continues to be room for “modified under arrangements” transactions that do not involve the joint venture in providing any clinical component of the service. Moreover, as noted above, after Oct. 1, 2009, neither space nor equipment may be furnished by such a joint venture on a percentage or per click basis.

### Diagnostic Testing Arrangements

The new anti-mark-up rules and IDTF rules will also impact certain collaborative diagnostic testing arrangements with oncologists. In particular, the new anti-mark-up rules will prohibit an oncologist or oncology group from marking-up to the Medicare program any professional or technical component service (such as the technical or professional component of a PET, CT, or MRI scan) that is obtained from an outside physician or supplier (such as a radiologist or IDTF) that does not “share a practice” with the oncologists. The radiologist, in this example, would not share a practice with the oncologists unless 75 percent of the radiologist’s services are provided through the oncology group in the same building in which the oncology group practices. Under the new rules, the oncologists would have to conduct and supervise the procedure (i.e., provide and supervise the radiation technologist) in order to mark-up and profit from it. These new requirements will

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make it more difficult for oncologists to profit on purchased professional or technical component services.

The new IDTF standards will also make it even more difficult for oncologists to profit from services purchased from an IDTF. Those new standards prohibit a fixed-site IDTF (i.e., a fixed-site imaging facility, such as a PET, MRI, or CT facility, that is enrolled in the Medicare program) from sharing space, equipment, or operations with an oncologist or oncology group. This rule will prevent fixed-site IDTFs from entering into shared or block lease arrangements with oncologists. Existing arrangements of this sort were generally required to be restructured as of Jan. 1, 2008. The new IDTF rules also require mobile imaging providers (e.g., mobile ultrasound, x-ray, CT, PET, or MRI providers) that are certified as IDTFs to bill Medicare separately for the technical component of the services they provide. This requirement means that an oncologist who obtains imaging services from a mobile IDTF can no longer bill Medi-

care on a global basis, nor bill for the technical component of the imaging service that the oncologist obtains from the mobile supplier.<sup>6</sup>

In conclusion, while recent legal developments at the federal level have narrowed somewhat the options for structuring business arrangements among oncology providers, multiple opportunities to establish legally defensible collaborative cancer care ventures remain. With careful business and legal planning, the goal of organizing cancer care providers to furnish coordinated, high-quality, cost-efficient, and profitable cancer care services in a legally compliant manner can still be achieved. □

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## References

<sup>1</sup>Final Stark Phase III Rule, *Federal Register* 72(171): 51012, effective December 4, 2007. Additional proposed rules, including proposed Incentive Payment and

Cost Savings Exception, *Federal Register* 73(130). Additional final Stark rules, *Federal Register* 73(161).

<sup>2</sup>OIG Adv. Op. 08-10 (August 19, 2008).

<sup>3</sup>Proposed and final anti-mark-up rules, 42 C.F.R. §§ 414.50 and 424.80. *Federal Register*. 72(227): 66401, 66404. *Federal Register*. 73(130): 38606. *Federal Register*. 73(224): 69935. Proposed and final IDTF rules, 42 C.F.R. § 410.33(g)(15). *Federal Register*. 72(227): 66398. *Federal Register*. 73(130): 38603-4. *Federal Register*. 73(224): 69933.

<sup>4</sup>42 C.F.R. § 411.356(a) and (c)(1)

<sup>5</sup>42 C.F.R. § 4.11.355(b)

<sup>6</sup>CMS recently posted an answer to a frequently asked question in which the agency clarifies that an oncology group can still bill on a global basis for equipment and tech services that the oncologists lease from a mobile equipment leasing company that is **not enrolled as an IDTF**. Available online at:

[https://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std\\_adp.php?p\\_faqid=9511&p\\_created=1229355972&p\\_sid=vMNqGxIj&p\\_accessibility=0&p\\_redirect=&p\\_lva=&p\\_sp=cF9zcmNo-PSZwX3NvcnRfYnk9JnBfZ3JpZHNvcnQ9NDoyJnBfcm93X2NudD0yMTE1LDIxMTUmcF9wcm9kc20mcF9jYXRzPSZwX3B2PSZwX2N2PSZwX3NlYXJjaF90eXBlPWfuc3dlnMuc2-VhcmNoX25sJnBfcGFnZT0x&p\\_li=&p\\_topview=1](https://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=9511&p_created=1229355972&p_sid=vMNqGxIj&p_accessibility=0&p_redirect=&p_lva=&p_sp=cF9zcmNo-PSZwX3NvcnRfYnk9JnBfZ3JpZHNvcnQ9NDoyJnBfcm93X2NudD0yMTE1LDIxMTUmcF9wcm9kc20mcF9jYXRzPSZwX3B2PSZwX2N2PSZwX3NlYXJjaF90eXBlPWfuc3dlnMuc2-VhcmNoX25sJnBfcGFnZT0x&p_li=&p_topview=1). Last accessed Feb. 2, 2009.

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