

The Stark Final Rule and Recent Developments in Block Leasing

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Who are the Fraud Busters?

- Department of Justice
- Office of Inspector General
- Centers for Medicare and Medicaid ("CMS")
- Third Party Payors (e.g. BCBS, Aetna)
- Other Federal and State Agencies
- Whistleblowers and other Third Party Individuals

Anti-Kickback Statute

- The Federal Anti-Kickback Statute (AKS) (42 U.S.C. § 1320a-7b(b)) prohibits the offering, paying, soliciting, or receiving of any remuneration in return for:
 - Business for which payment may be made under a federal health care program; or
 - Inducing purchases, leases, orders or arranging for any good or service or item paid for by a federal health care program
- Remuneration includes kickbacks, bribes and rebates, cash or in kind, direct or indirect, and you have to have the intent for the remuneration to be a kickback
- Criminal and civil penalties for an Anti-Kickback violation -- \$25,000 per criminal offense, imprisonment of up to 5 years and civil monetary penalties

STARK LAW

- The Stark Law (42 U.S.C. § 1395nn) prohibits a physician from referring Medicare patients for certain “designated health services” (“DHS”) to entities with which the physician (or any of his or her immediate family members) has a financial relationship, unless an exception applies. This is a strict liability law.
- The Stark Law excludes from the definition of “referral” a request by a radiation oncologist for radiation therapy.
- The designated health services covered by Stark include clinical laboratory, physical therapy, occupational therapy, outpatient prescription drugs, radiology and certain other diagnostic imaging services (e.g. PET scans), radiation therapy services and supplies, DME and other supplies, and outpatient and inpatient hospital services.

Final Rule

- On September 5, 2007, CMS issued final regulations governing Stark II (72 Fed. Reg. 51012) These final regulations are referred to as Stark II, Phase III, and were thought by many to complete the formal Stark rulemaking process.
- In August 2008, however, CMS modified Stark in its publication of the 2009 Final Hospital Inpatient Prospective Payment Systems Rule (the "Final Rule") (73 Fed. Reg. 48433).
- The Final Rule contains several significant modifications to payments received by hospitals and physicians, some of which do not take effect until October 1, 2009.
- The Final Rule will require physicians, hospitals and other healthcare providers to unwind and restructure certain existing relationships.

SIGNIFICANT ASPECTS OF THE FINAL RULE

- The major points of the Final Rule:
 - "Stand in the Shoes" Provisions
 - Disallowance Period
 - Percentage-Based Leasing
 - "Per-Click" Leasing
 - Services Provided Under Arrangements

Stand in the Shoes

Overview

- Physicians that refer DHS to a DHS entity are treated as standing in the shoes (“SITS”) of their physician organization when analyzing the financial relationship between the physician and the DHS entity under Stark.
- A physician is deemed to stand in the shoes of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if:
 - The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and
 - The physician has an ownership or investment interest in the physician organization.
- Physicians with only a “titular ownership interest” (those without the ability or the right to receive the financial benefits of ownership) are not required to stand in the shoes of their organizations.
- Non-owner physicians may, but are not required to, stand in the shoes of their physician organization.
- Example: If an entity owned by three radiation oncologists contract with an ROC, radiation oncologists each SITS with the ROC.

Implications of SITS

- If a physician stands in the shoes of his or her physician organization, the physician (and the DHS entity) will have to satisfy a direct Stark exception with regard to the financial relationship between the physician organization and the DHS entity to which the physician refers.

SITS Exceptions

- Hospitals and other Part A providers of services
- Federally qualified health centers
- A single legal entity (that does not satisfy the requirements of a group practice for purposes of 42 CFR §411.352) that operates a faculty practice plan AND either a medical school or hospital, or both
- A medical school that does not operate a faculty practice plan but employs physicians to provide clinical and academic services

PERIOD OF DISALLOWANCE

Noncompliance

- The time period for which a financial relationship between a referring physician and DHS entity fails to satisfy all of the requirements of an exception to Stark is referred to as the “period of disallowance.” CMS placed an outside limit on the period of disallowance in certain circumstances.
- For arrangements that are non-compliant for reasons other than compensation, the latest period of disallowance is the date when the arrangement was brought into compliance.
- For arrangements that are non-compliant due to compensation, the latest period of disallowance is the date on which the compensation differences were resolved. 73 Fed. Reg. 48751.

UNSIGNED DOCUMENTS

- CMS also finalized a special rule regarding noncompliance with Stark due to a failure to execute the necessary documents.
- The Final Rule allows documents to meet Stark requirements if they are signed within 90 days after a deal becomes noncompliant, if the missing signatures were inadvertently not obtained, or within 30 days if the failure to obtain the signatures was not inadvertent.

UNDER ARRANGEMENTS

GENERALLY

- Stark – Phase I definition of an entity included only the person or entity that billed Medicare for DHS, but not the person or entity that performed DHS where the person or entity performing the DHS is not the person or entity billing for it. In this case the party performing the services was said to be doing so “under arrangement” with the billing party (typically a hospital where its billing rates are higher than for free standing facilities).
- “Under Arrangement” transactions with the service provider being a joint venture including physicians or a physician group practice became popular as a way to allow physicians to effectively joint venture with the hospital using the hospital’s billing rates.
- In 2008, CMS made known its continuing concern about the risk of overutilization with respect to services performed “under arrangement.”
- Under arrangements was popular with radiation oncology, particularly with urologists seeking a way to profit from IMRT referrals.

FINAL RULE ON UNDER ARRANGEMENTS

- Under the Final Rule, CMS eliminated most “under arrangement” transactions, effective October 1, 2009, by expanding the definition of “entity” to also include entities that “perform” services that are in turn billed as DHS by another entity. Since both parties are DHS Entities as to the service, the relationship will now violate Stark. 73 Federal Register 48721-48730 (2008).
- CMS purposely declined to define the meaning of “perform the service” but its response to certain comments provides guidance. To perform essentially means to provide medical work in such a manner that the performing entity could bill for the service but arranges for another entity to do so.
- On the other hand, an entity that only leases or sells space or equipment, or only provides management services, or only provides personnel or supplies, does not “perform” DHS.

WHAT TO DO NOW?

- IN RADIATION ONCOLOGY, FREE STANDING CENTER HOSPITAL/PHYSICIAN JOINT VENTURES WITH NON-REFERRERS (E.G., RADIATION ONCOLOGISTS) WILL WORK.
- GROUP PRACTICES CAN STILL OWN ROCS.
- HOSPITAL/PHYSICIAN JOINT VENTURES WITH REFERRING PHYSICIANS INCLUDED (E.G., ONCOLOGISTS OR UROLOGISTS) STILL MIGHT WORK IN CERTAIN STATES (E.G., FLORIDA) WHERE HOSPITALS CAN OWN AN INTEREST IN GROUP PRACTICES.
- MANAGEMENT AGREEMENTS, EQUIPMENT AND SPACE LEASING VENTURES, AND BILLING COMPANIES, CAN BE JOINT VENTURED
- LOOK AT SCOPE OF UNDER ARRANGEMENT. FOR EXAMPLE, AN AGREEMENT BETWEEN A FREE STANDING CENTER AND A HOSPITAL TO PROVIDE RADIATION TO HOSPITAL PATIENTS AND BE COMPENSATED FROM HOSPITAL DRG IS TECHNICALLY AN UNDER ARRANGEMENT TRANSACTION, ALTHOUGH LIKELY OK.

OIG ADVISORY OPINION 08-10

- OIG Advisory Opinion 08-10 (Advisory Opinion) addresses a block leasing arrangement between a radiation oncology center owned by a group practice, and a urology group (involving IMRT), and determines that the arrangement presents serious problems and is thus problematic.
- The Advisory Opinion addresses the application to the transaction of the AKS, and not Stark.
- At the back of this presentation is a short discussion of the Advisory Opinion.
- The Advisory Opinion certainly has an adverse effect on many block leases, but not necessarily all of them.
- If there is not, for example, a prior referral relationship between the parties, a block lease may still be possible.

"PER CLICK" COMPENSATION ARRANGEMENTS

Generally

- 'Per Click"- when payments are made on a per-use, per-service or unit-of-time basis.
- In 2007 and 2008, CMS proposed that the Stark exception for space and equipment leases **not** include "per click" payments to a physician lessor for services rendered by an entity lessee to patients who the physician refers to the center.
- Under the Final Rule, effective Oct. 1, 2009, CMS will prohibit *many* but *not all* per-click lease arrangements. The Final Rule per-click prohibitions will apply to lease payments made on or after October 1, 2009. 73 Federal Register 48713-48721 (2008).

Final Rule- Generally

- The Final Rule revised exceptions for:
- Rental of office space- 42 C.F.R. §411.357(a)
- Rental of equipment – 42 C.F.R. §357(b)
- Fair market value compensation arrangements – 42 C.F.R. §411.357(l)
- Indirect compensation arrangements – 42 C.F.R. §411.357(p)

What the Final Rule Prohibits

- CMS states that per-click arrangements for rental of space and equipment must be FMV and commercially reasonable. (i.e. a lease arrangement will not meet these requirements if a lessee is “paying a physician substantially more for a lithotripter or other equipment and a technologist than it would have to pay a non-physician-owned company for the same or similar equipment or service.”)
- There is a “serious question” of commercial reasonableness if lessee is performing a sufficiently high volume of procedures that make it economically feasible to purchase equipment rather than to lease from a physician or entity.

Prohibitions

- The Final Rule bans per-click lease payments from physician lessors (or physician-owned lessors) to DHS entities for services the entities render to those physicians' patients.
- CMS also invalidates per-click transactions in which the DHS entities are lessors to a physician or a physician entity lessee.
- CMS states that "on demand" rental agreements are effectively per-click or per-use arrangements and thus are now prohibited for lease of space and equipment to the extent that the charges reflect services provided to patients referred between the parties.

What is not prohibited

- Per-Click compensation arrangements involving non-physician-owned lessors to the extent that such lessors are not referring patients for DHS
- Per-Click payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors.
- CMS, however, reminds stakeholders that all such arrangements must satisfy all of the requirements of lease exceptions (i.e. fair market value and commercially reasonable)
- CMS declined to invalidate all time-based leasing arrangements (i.e. block time leases) but cautioned that the same concerns that arise with per-click arrangements can arise with certain time-based lease arrangements (i.e. leasing space or equipment once a week or for a couple of hours)- therefore, block leases should be carefully structured.

What to do now?

- Service arrangements instead of lease arrangement- (Provision of global services)
- Difficulties of splitting lease from service fees

PERCENTAGE- BASED COMPENSATION ARRANGEMENTS

Generally

- **Percentage based compensation is the use of a compensation formula based on a percentage of revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated.**
- In Stark, Phase II, CMS allowed physicians to earn percentage-based compensation for physician services they personally performed — and obtain a productivity bonus on any such services.
- In 2007, CMS proposed to ban percentage-based compensation in such arrangements.
- Under the Final Rule, effective October 1, 2009, these compensation arrangements are not banned, but physicians and DHS entities will not be able to use percentage-based compensation formulae to decide rental charges for office space and equipment. The Final Rule percentage-based prohibitions will apply to lease payments made on or after October 1, 2009. 73 Federal Register 48709-48713 (2008).

Final Rule- Generally

- As with “per-click” compensation arrangements, the Final Rule revised exceptions for:
 - Rental of office space- 42 C.F.R. §411.357(a)
 - Rental of equipment – 42 C.F.R. §357(b)
 - Fair market value compensation arrangements – 42 C.F.R. §411.357(l)
 - Indirect compensation arrangements – 42 C.F.R. §411.357(p)

What the Final Rule Prohibits

- The Final Rule's prohibition extends to lease relationships that would fall under both the direct compensation and the indirect compensation Stark exception (i.e. relationships between physician-owned leasing companies and DHS entities).

What is not prohibited

- Personally performed physician services — clinical and administrative.
- But, CMS WARNS it will continue to monitor compensation formulae in arrangements between DHS entities and referring physicians, such as management agreements and, if appropriate, may further restrict percentage-based formulae in a future rulemaking.

What to do now?

- Service arrangements instead of lease arrangements-(Provision of global services)
- Difficulties of splitting lease from service fees

BLOCK LEASING

BLOCK LEASING -- NOT ADDRESSED BY FINAL RULE

- A Block lease is typically a lease of a block of time (i.e., one day per week) at a facility by a medical group or other entity, during which period the leasing entity performs the same types of services at the center that occur the rest of the week.
- Typically, the block lease provides that not only is the facility leased, but so are the personnel and the equipment, supplies are provided, and often the lessor bills and collects for the lessee.
- IDTFs (Independent Diagnostic Testing Facilities) may **not** block lease. However, diagnostic centers owned by medical group practices and operated within the Stark "in-office ancillary services" exception (minimum 4 hour lease), can do so. So can non-diagnostic businesses like radiation oncology centers.
- Block leasing was not discussed or addressed in the Final Rule.

PHYSICIAN PRESENCE RULES: HOSPITAL OUTPATIENT SERVICES

CMS rule- “incident to” services

- Longstanding Medicare regulations require hospitals to provide covered “incident to” hospital outpatient services under the direct supervision of a physician.

CMS Rule- codified

- 42 C.F.R. §410.27(f)- Services furnished at a location that CMS designates as a department of a provider under §413.65 must be under direct supervision of a physician. “Direct supervision” means that the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure.
- Medicare Benefit Policy Manual, ch. 6, §20.5.1 - The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises. The hospital medical staff that supervises the services need not be in the same department as the ordering physician. However, if the services are furnished at a department of the hospital which has provider-based status in relation to the hospital under 42 C.F.R §413.65 of the Code of Federal Regulations, the services must be rendered under the direct supervision of a physician.

CMS responds to comments

- We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital. The effect of the regulations in this final rule is to extend this assumption to a department of a provider that is located on the campus of the hospital. However, the regulation *does not* extend the assumption of supervision to a department of a hospital that is located off the campus of the hospital. 65 Fed. Reg. 18434, 18525 (April 7, 2000) (emphasis added).

CMS clarifies rule

- CMS' new position, effective January 1, 2009, backs away from its previous position that in essence "deemed" hospitals and on-campus outpatient departments to have met the direct supervision requirement for incident-to billing.
- CMS explained its 2009 OPSS Final Rule as follows:

... we were concerned that some stakeholders may have misunderstood our use of the term "assume" in the April 7, 2000 OPSS final rule with comment period, believing that our statement meant that we do not require any supervision in the hospital or in an on-campus provider-based department for therapeutic OPSS services, or that we only require general supervision for those services. **This is not the case.**

..... It has been our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital. 73 FR 4158, 4159 (July 18, 2008) (proposed rule); 73 FR 68702-68704 (November 18, 2008) (final rule) (emphasis added).

Clarification Conclusion

- CMS seems to require direct supervision of incident to services provided at a hospital outpatient department to be the same, regardless of whether the outpatient department is on the hospital's main campus or at provider- based locations.

What to do now?

- For provider-based departments, a supervising physician must be “on the premises of the location” of the outpatient department.
- Starting point for hospitals would be to review previously submitted provider-based attestations to ensure that they accurately describe the space in which the hospital outpatient services are provided since it is foreseeable that CMS may use such attestations to define “on the premises of the location” in the future.
- For services furnished at the hospital itself, it is unclear whether CMS will require that a physician be housed in every department in order for outpatient services furnished in such areas to be covered.
- Absent any further clarifications, however, hospitals should monitor their operations to ensure physician presence in all areas of the hospital or risk potential recoupment of alleged Medicare overpayments.

PHYSICIAN SUPERVISION RULES: FREE STANDING CLINICS

CMS Rule- “incident to” services

- No current clarifications or changes have been made to these rules.
- Medicare Benefit Policy Manual, Ch. 15, section 60 still governs these types of services conducted in free standing clinics.
- Different state laws may have carve-outs for radiation therapy services

Setting and Services Defined

- **§60(a)- Noninstitutional Setting** - A non-institutional setting means all settings other than a hospital or skilled nursing facility in which a physician is providing services.
- **§60(a)- To be covered incident to the services** of a physician or other practitioner, services and supplies must be:
 - An integral, although incidental, part of the physician's professional service (§60.1);
 - Commonly rendered without charge or included in the physician's bill (§60.1A);
 - Of a type that are commonly furnished in physician's offices or clinics (§60.1A);
 - Furnished by the physician or by auxiliary personnel (i.e. any individual who is acting under the supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician) under the **physician's direct supervision (§60.1B)**.

Clinic defined

- **§60.3- Clinic-** A physician directed clinic is one where:
- A physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open;
- Each patient is under the care of a clinic physician; and
- The nonphysician services are under medical supervision.

Direct Supervision Defined

- **§60.1B** - Direct supervision in the office setting does not mean that the physician must be present in the same room with his or her aide.
- However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services.

Direct Supervision- Auxiliary Personnel

- If auxiliary personnel perform services outside the office setting (other than in a hospital or skilled nursing facility), their services are covered incident to a physician's service only if there is direct supervision by the physician.
- For example, if a nurse accompanied the physician on house calls and administered an injection, the nurse's services are covered. If the same nurse made the calls alone and administered the injection, the services are not covered (even when billed by the physician) since the physician is not providing direct supervision.
- Services provided by auxiliary personnel in an institution (e.g., nursing, or convalescent home) present a special problem in determining whether direct physician supervision exists. The availability of the physician by telephone and the presence of the physician somewhere in the institution does not constitute direct supervision. **§70.3 of the Medicare National Coverage Determinations Manual**
- For hospital or skilled nursing facility patients who are in a Medicare covered stay, there is no Medicare Part B coverage of the services of physician-employed auxiliary personnel as services incident to physicians' services under §1861(s)(2)(A) of the Act. Such services can be covered only under the hospital or skilled nursing facility and payment for such services can be made to only the hospital or skilled nursing facility by a Medicare intermediary. **§80 of the Medicare Benefits Policy Manual.**

Clinics - Specifically

- In highly organized clinics, particularly those that are departmentalized, direct physician supervision may be the responsibility of several physicians as opposed to an individual attending physician.
- The physician ordering a particular service need not be the physician who is supervising the service.
- Supplies provided by the clinic during the course of treatment are also covered.

Services of Non-Physicians

- §60.2- Nonphysician practitioners - certified nurse midwives, clinical psychologists, clinical social workers, physician assistants, nurse practitioners, and clinical nurse specialists.
- Services performed by these nonphysician practitioners incident to a physician's professional services include not only services ordinarily rendered by a physician's office staff person (e.g., medical services such as taking blood pressures and temperatures, giving injections, and changing dressings) but also services ordinarily performed by the physician such as minor surgery, setting casts or simple fractures, or reading x-rays.
- In order for services of a nonphysician practitioner to be covered as incident to the services of a physician, the services must meet all of the requirements for coverage- **services must be an integral, although incidental, part of the physician's personal professional services, and they must be performed under the physician's direct supervision.**

Non-Physicians- cont'd

- Each occasion of an incidental service performed by a nonphysician practitioner need not always be the occasion of a service actually rendered by the physician.
- There must, however, have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part, and there must be subsequent services by the physician of a frequency that reflects the physician's continuing active participation in and management of the course of treatment.
- The physician must also be physically present in the same office suite and be immediately available to render assistance if that becomes necessary.
- A physician might render a physician's service that can be covered even though another service furnished by a nonphysician practitioner as incident to the physician's service might not be covered.
- For example, an office visit during which the physician diagnoses a medical problem and establishes a course of treatment could be covered even if, during the same visit, a nonphysician practitioner performs a noncovered service such as acupuncture.

CMS Rule- Diagnostic Testing

- As stated previously, CMS continues to follow the supervision requirements for individual diagnostic tests as listed in the Medicare Physician Fee Schedule.

Is Block Leasing a Thing of the Past or did OIG Advisory Opinion 08-10
Merely Recite the OIG's 2003 Special Advisory Bulletin?

By: Mike Segal, Esq. and Heather Siegel, Esq.
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For years physicians have been engaging in block leasing arrangements with physician group practices and other healthcare entities, including, from time to time, radiation oncology centers. Last year, the Office of Inspector General ("OIG") issued Advisory Opinion 08-10 ("08-10"), which analyzed a block lease arrangement between a urology group and a radiation oncology center, and did not reach a favorable conclusion. Since then, lawyers across the country have been writing articles questioning whether 08-10 limits the ability of healthcare business to rely upon the Federal Anti-Kickback Statute ("AKS") safe harbors, and thus prevents physicians from being afforded safe harbor protection in block leasing arrangements. Does 08-10 put an end to block leasing arrangements? Not necessarily. Will these arrangements need to be carefully crafted to comply with the AKS in the future? Absolutely.

In 08-10, a urology group proposed to lease space, equipment, management and personnel from a radiation oncology center (owned by an oncology group) for a specific block of time, one day each week, in order to provide radiation oncology therapy ("IMRT") to its patients suffering from prostate cancer. The urology group and the radiation oncology center had a pre-existing referral relationship whereby the urology group, a major referrer to the center, would refer patients to the center for IMRT. The intent of the block lease was to allow the urology group to be able to refer its IMRT patients to its own part-time radiation oncology center, and thus hopefully profit from those referrals. The urology group would profit by receiving the difference between the third-party payor reimbursements and the fees it paid to the radiation oncology center regarding the block lease ("the Profit"). While the oncology group would presumably no longer receive referrals from the urology group, it would receive lease payments that otherwise it would not have been paid.

The block lease arrangement appeared to satisfy the criteria of the AKS personal services and management safe harbor ("Services Safe Harbor"), and, in addition, was apparently structured to allow the urology group to satisfy the Stark "in-office ancillary services" exception. The OIG never reached any conclusion on that issue, believing it was unnecessary to do so. Instead, the OIG focused on the Profit. The OIG stated that even if the block lease agreement itself met the Services Safe Harbor, the Profit earned by the urology group was outside of the Services Safe Harbor. It felt that the Profit was likely a disguised payment for referrals and was thus suspect.

Cont'd.

While many lawyers across the country have argued that 08-10 is a departure from the government's intent that meeting the Services Safe Harbor affords absolute protection to an arrangement, we believe that there is only one thing that is clear from 08-10 – the government does not want physicians and healthcare entities to engage in any indirect activity if such activity would be illegal if done directly and, notwithstanding any AKG Safe Harbors, will look for opportunities to attack any arrangements it believes would result in this improper result.

During 2003 and 2004 the OIG issued a Special Advisory Bulletin (the "Bulletin") and an Advisory Opinion that at least to some extent, relate to block leasing. *See 2003 Special Advisory Bulletin* and *OIG Advisory Opinion 04-17*. The 2003 Advisory Bulletin holds that when a healthcare provider substantially contracts out an entire operation of a related line of business to a lessor, and the healthcare provider receives profits of that business from its patient referrals, the OIG will presume that the contractual relationship is questionable and will examine such relationship closely. The OIG specifically stated in the Advisory Bulletin that even if such a contractual relationship fit within the Services Safe Harbor, only the remuneration flowing from the healthcare provider to the lessor would be protected; but the Services Safe Harbor would not protect the profit earned by the healthcare provider after receiving payment from a federal health care program.

The OIG confirmed its position on questionable joint ventures and block leasing a year later in Advisory Opinion 04-17 ("04-17"). In 04-17, an entity ("Entity") that provided pathology laboratory services, including all management, administrative services, equipment, and professional personnel associated with such services, wanted to enter into a series of contracts with physician group practices. In return, the physician groups would pay the Entity a flat, monthly fee, a per-specimen fee, and a fee for billing and collection services. The monthly fee would be set at an amount that took into consideration historical utilization data. An affiliate of the entity already had a pre-existing referral relationship with most of the physician group practices. At the time, the affiliate already provided these services and additional pathology laboratory services. If the Entity contracted with the physicians, it was assumed that the physicians would continue to make referrals to the Entity's affiliate, which provided and would continue to provide the additional pathology laboratory services. The OIG, similar to its opinion in 08-10, stated that "by agreeing effectively to provide services [that the Entity or the affiliate] could otherwise provide in its own right for less than the [remuneration paid to it by the physician group practices], the [Entity] would potentially be providing a [the physician group practices] with the opportunity to generate a fee and a profit." It was noted that the Services Safe Harbor would not apply to the profit earned by the physician group practices. 08-10 is basically an extension of the concepts set forth in 04-17.

Cont'd.

It appears that the OIG, in issuing the Advisory Bulletin, was trying to convey to the healthcare community that if the profit earned by a healthcare provider is not protected by the Services Safe Harbor, the government will then examine the intent of the parties. If the intent of the parties is payment for referrals or to secure a stream of referrals, the OIG will deem the profit earned by the healthcare provider to be a kickback.

Whenever a block lease arrangement is proposed, the “sniff test” is a good indicator of how the government will react if the relationship comes under scrutiny. If, for example, there is not a prior referral pattern between the lessor and the lessee, the block lease arrangement may be free from challenge. If the true intent is to protect a referral source or to pay for referrals, the government will work diligently to argue that the relationship was consummated with the intent to provide a kickback.

End.