PROVIDER SERVICES OBTAINED "UNDER ARRANGEMENTS" STARK, ILLEGAL REMUNERATION, AND PROVIDER-BASED RULES

By
Catherine T. Dunlay
Dennis Barry[1]

I. MEDICARE PAYS HOSPITALS MORE THAN OTHER SUPPLIERS FOR THE SAME SERVICES, AND SOME SERVICES ARE NOT COVERED AT ALL UNLESS FURNISHED BY A HOSPITAL

1.1 Different Payment Rates for the Same Service in Different Settings

A. Hospitals, IDTFs and Physician Offices—Medicare pays hospitals for outpatient diagnostic testing (other than clinical laboratory services) under outpatient PPS while Medicare pays independent diagnostic testing facilities (IDTFs) and physicians for diagnostic testing under the RBRVS fee schedules. Similarly, Medicare pays differently for the same outpatient surgical services depending on whether the service is furnished in a hospital or an ambulatory surgical center (ASC). In no cases does Medicare pay a hospital less, and in some instances, Medicare pays a hospital substantially more.

B. Medicare's policy is not as irrational as it initially appears. Hospitals are held to higher facility standards than other facilities. In addition, the Medicare cost allocation formula forces the allocation of costs among services in a manner that may overstate the costs of some outpatient services and understate the costs of inpatient services. Regardless of whether Medicare's payment policy makes sense or not, it appears that the differentials in payment among sites will continue for the foreseeable future. In some instances, other payers also pay more to hospitals than to other entities for the same services.

1.2 Coverage Differences Depending on Setting

A. Medicare's "inpatient only" list specifies services that will not be covered if furnished in any setting other than a hospital outpatient setting.

B. Certain surgical services covered in either an ASC or a hospital will not be covered if furnished in a physician's office.

---

[1] Dennis Barry gave a similar presentation on this topic at the AHLA program for Academic Medical Centers, in January, 2008. Robert Homchick, a partner in Davis Wright Tremaine in Seattle, Washington participated as a co-speaker with Mr. Barry in that prior presentation. Mr. Homchick helped Mr. Barry consider more fully the issues covered in Mr. Barry's portion of this presentation and deserves credit for that. Some of Mr. Barry's portion of this outline bears some similarity to that prior presentation which reflects input from Mr. Homchick.

C. IDTFs can furnish *diagnostic* services but there is no Medicare coverage for therapeutic services. This has especial significance with respect to cardiac catheterization services since it is not always known prior to the procedure whether interventional therapeutic services will be needed. [2]

1.3 Supervision Requirements--The Medicare requirements for physician supervision vary. For all services for which the Medicare basis for coverage is as a service "incident to" a physician service, there must be some degree of physician supervision. That physician supervision is "assumed" to be furnished for hospital outpatient services furnished on the hospital's main campus, *see* 65 Fed. Reg. 18434, 18525 (Apr. 7, 2000) and Intermediary Man., Pt. III, § 3112.4, but is not assumed to be furnished in off-campus provider-based sites or in physician offices.

1.4 As a result of Medicare's more favorable payment for services billed by hospitals and its limitations on physicians having an ownership interest (or its ilk) in a hospital department, there is an incentive for physicians and providers to enter into transactions whereby services can properly be covered by Medicare as "hospital services" although furnished by a nonhospital entity (possibly including physician investors). This outline and presentation will focus on both the current Medicare rules and how those rules may change in the foreseeable future.

II. OVERVIEW OF DIFFERENCES BETWEEN "UNDER ARRANGEMENTS" COVERAGE AND PROVIDER-BASED STATUS

2.1 "Under Arrangements" Services--From the outset of the Medicare program, the statute and regulations have expressly authorized payment for services furnished under arrangements between a provider and an outside vendor. 42 U.S.C. § 1395x(w) (definition of "under arrangements") and *e.g.,* 42 U.S.C. § 1395x(b)(3) which expressly includes coverage for services furnished under arrangements. Often these arranged for services were furnished in locations that were not part of the provider. By definition, the personnel furnishing the services were not provider personnel. Nonetheless, as long as the provider exercised some oversight over the vendor, Medicare has routinely covered arranged for services and has reimbursed the provider for those services. In marked contrast to the provider-based rules, it has never been a requirement that an under arrangement vendor had to be "integrated" with a provider or meet specific detailed standards.

2.2 Existence of Under Arrangements Coverage Appears to Subvert the Stringent Requirements of Provider-Based Status—In contrast to coverage for under arrangements services, the concept of "provider-based" status is not addressed in the statute (except in 2000 amendments reacting to the final provider-based regulation). The agency perceived a need to distinguish between services that

[2] There are legal and policy arguments why interventional cardiology services should be covered in freestanding cardiac catheterization centers, but the prevailing view is that these freestanding centers qualify to participate in Medicare as independent *diagnostic* testing facilities ("IDTF"), and therapeutic procedures are not covered when furnished in an IDTF.

would be paid as hospital services and those services, which although furnished by the same legal entity that operated a hospital, would not be paid for as hospital services. The provider-based rules evolved from general guidelines issued in the 1970s to more specific and extensive requirements issued in a 1996 Program Memorandum and were ultimately reflected in the provider-based regulation published as part of the outpatient PPS rulemaking in April 2000. 65 Fed. Reg. 18434, 18504 *et seq.* (Apr. 7, 2000). Historically, the relevance of provider-based status was two-fold: 1) services would be covered and paid for as hospital services; and 2) hospital overhead costs would be allocated to the service for purposes of Medicare cost reimbursement. Except for critical access hospitals which remain cost reimbursed, the allocation of hospital overhead costs to provider-based departments is now irrelevant. The obvious question is whether under arrangements coverage offers an avenue to attain Medicare hospital payment rates while avoiding the application of the more detailed and stringent provider-based rules.

2.3 CMS has made no attempt to reconcile what some may view as inconsistencies between its rules for provider-based status and under arrangements coverage. There are definitely, however, situations when Medicare will cover, as hospital services at hospital payment rates, services furnished by an under arrangements vendor that are not furnished in a provider-based location and which do not meet the provider-based standards.

III. UNDER ARRANGEMENTS COVERAGE

3.1 Services that Can Be Furnished Under Arrangements

A. Preamble language suggests that under arrangements coverage exists for "limited" or specialized services, but nothing in the statute or regulations limits under arrangements coverage in this manner. *See, e.g.,* 63 Fed. Reg. at 47592 (Sept. 8, 1998) and 65 Fed. Reg. at 18520 (Apr. 7, 2000).

B. Blue Cross Administration Bulletin #1347 (Apr. 10, 1979) is reported[3] to limit under arrangements coverage. Presumably with HCFA's approval, the Blue Cross Association interpreted the law to prohibit the following services from being furnished under arrangement:

(1) Coronary intensive care;
(2) Pharmacy drugs;
(3) Central supply items;
(4) IV solutions; and
(5) Operating rooms.

[3] The Blue Cross and Blue Shield Association no longer has a copy of this 1979 Administrative Bulletin, and the author was unable to locate a copy anywhere. In the "hospital within a hospital" regulations, CMS has, under one of three options for qualifying as a separate hospital that may be excluded from Medicare PPS defined certain basics elements of patient care by reference to the hospital conditions of participation. 42 C.F.R. § 412.22(e)((1)(v)(A). Although those regulations have no bearing on under arrangements coverage, CMS may view the services enumerated in that regulation as being the services that may not properly be obtained under arrangements.

In arriving at its interpretation that certain "core" hospital services cannot be furnished by a third-party, BCA relied upon the statutory definition of "inpatient hospital services." 42 U.S.C. §§ 1395x(b)(1)-(2).

3.2 Hospital Outpatient Services

A. In contrast to hospital inpatient services, for which there is a single broad coverage regulation, Medicare coverage for hospital outpatient services is subject to many specific regulations with different provisions. For example:

- Services "incident to" a physician's services are covered under 42 C.F.R. § 410.27, and include most therapeutic services furnished to hospital outpatients such as day surgeries and cardiac catheterization. As discussed below, the literal wording of this coverage regulation for hospital outpatient services furnished "incident to" a physician's services limits coverage to those services furnished "in the hospital or at a location . . . that CMS designates as a department of the provider under § 413.65 [the provider-based regulation]." 42 C.F.R. § 410.27(a)(1)(iii).
- Diagnostic services furnished "by or under arrangements by a participating hospital" are covered under 42 C.F.R. § 410.28. In contrast to the coverage regulation applicable to hospital outpatient services that are "incident to" a physician's services, the coverage regulation for diagnostic services is silent as to the location of the service. CMS's Manual expressly states that there is coverage for diagnostic services not furnished within the hospital. Benefit Pol. Man. (CMS Pub. 100-02), Chpt. 6, § 20.3.2.
- Physical therapy, occupational therapy, and speech-language pathology services are covered under separate regulations which expressly permit coverage for under arrangement services and which are silent with respect to the location of those services. 42 C.F.R. §§ 410.60, 410.62.
- Radiation therapy services are covered under 42 C.F.R. § 410.35, and unlike many other coverage regulations, that regulation does not expressly cover those services under arrangements.
- A number of other bases of coverage apply to specific services that may be furnished in hospitals on an outpatient basis, e.g., partial hospitalization services (42 C.F.R. § 410.43) and mammography (42 C.F.R. § 410.34).

B. The first step in analyzing Medicare coverage for any under arrangement service is determining the regulatory basis of coverage for that specific service.

3.3 Medicare's Manual Requirements for Under Arrangement Billing and Payment

A. Medicare's General Information and Eligibility Manual, Chapter 5, § 10.3 (Sept. 11, 2002) sets forth the general requirement that ***"the provider must exercise professional responsibility over the arranged-for services."*** In exercising professional responsibility over the under arrangements services furnished to hospital patients, the manual specifies that ***a hospital must***:

- Apply the same quality controls over the under arrangements personnel that it would over its own employees;
- Register the patient and apply its standard admission policies;
- Maintain a complete and timely clinical record on the patient, which includes diagnoses, medical history, physician's orders, and progress notes relating to all services received;
- Maintain liaison with the under arrangement entity's attending physician; and
- Ensure that the medical necessity of the services is reviewed on a sample basis by the utilization review (UR) committee if one is in place, the facility's health professional staff, or an outside UR group.

B. In its manual, CMS emphasizes that under arrangements ***may not "merely serve as a billing mechanism for the other party."***[4] *Id.* The parties must ensure that the patients are bona-fide hospital patients. CMS defines "outpatient" as a person "who has not been admitted as an inpatient but who is registered on the hospital . . . records as an outpatient and receives services (rather than supplies alone) directly from the hospital. It is common for hospitals to bill for arranged-for services even when the hospital is not billing for any services that it has furnished directly. But with arranged-for services, the hospital exercises professional supervision over the services and, to date, CMS has not questioned whether this supervision is sufficient to render the patient a hospital outpatient. The prevailing interpretation is that when the hospital demonstrates the requisite oversight, that the hospital is not acting only as a billing agent, and that the arrangement does not serve to improperly circumvent other Medicare requirements.

3.4 Medicare Conditions of Participation--require the hospital's governing body to be responsible for services furnished to its patients under arrangements:

The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit

[4] Some health care attorneys have interpreted this language as barring any arrangement in which the under arrangements vendor is not itself enrolled in Medicare and bills Medicare for some services, i.e., services not furnished under arrangement to the hospital. Neither of the presenters for this session interprets this "billing mechanism" language in that manner.

the hospital to comply with all applicable conditions of participation and standards for the contracted services. (1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner. (2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided. 42 C.F.R. § 482.12(e).

3.5 Documentation of Professional Supervision"—Medicare instructions do not delineate with much specificity how a hospital should exercise "professional supervision" over arranged-for services, or how a hospital should document the existence of such supervision. A list of some activities that may possibly be viewed as indicia of professional supervision of a vendor by a provider follows. (This is not an exhaustive list,[5] and sometimes may not make sense in every circumstance.)

- The patient is registered as a hospital patient prior to receiving services from the under arrangements vendor, and receives the same notices and signs the same forms as a patient receiving services directly from the provider.
- The physician ordering services to be furnished by the under arrangements vendor is on the provider's medical staff and the services ordered are within the physician's scope of privileges.6
- The provider verifies that the vendor is Medicare certified and maintains documentation of that certification in the provider's permanent files, or alternatively, the provider maintains documentation of licensure and other quality requirements consistent with the provider's policy.
- The provider has a written contract with the vendor that reflects the provider's oversight with as much specificity as possible.
- The provider's administrator is responsible for the services furnished by the vendor reviews the vendor's policies and procedures at the outset of the arrangement. The vendor's policies and procedures for furnishing services should conform to the provider's policies and procedures and Joint Commission requirements for services provided under contractual arrangements.
- If the vendor furnishes the services off-hospital premises, the provider administrator responsible for the services furnished by the vendor should visit the vendor's premises prior to the beginning of the arrangement and periodically thereafter, and review with a vendor manager compliance with appropriate quality standards.7

[5] First published in *Dennis Barry's Reimbursement Advisor,* Apr. 2007.
[6] This is not a requirement; hospitals can furnish covered diagnostic services on the order of a physician who is not on the hospital's medical staff. Implementing this policy would, however, help to strengthen the provider's claim that it exercises professional supervision.
[7] *See* Stds. ACC-5, LD.3.50, Joint Comm'n Comp. Accreditation Man. for Hosps. (updated Sept. 2006).

- The entire medical record of services furnished at the vendor including, without limitation, orders, notes, and test results is created in a manner consistent with the provider's rules and Joint Commission standards applicable to the provider's medical records, and a legible copy of that record is transmitted to the provider in the same time frames as services furnished directly by the provider.
- The under arrangements vendor immediately completes incident reports on the provider's patients whenever such a report would be required if an event occurred in the provider and transmits such reports to the provider upon completion of the report.
- The provider committees on utilization review, infection control, and any other relevant committees, shall review care furnished to hospital patients by the under arrangements vendor on the same basis as they review care furnished directly by the hospital.

3.6 Medicare Certification and Enrollment Requirements for the Entity Furnishing Under Arrangements Services

CMS's Manual explains that only providers or suppliers seeking payment directly from Medicare must enroll in the program:

Physicians, suppliers, organizations, etc., that wish to be reimbursed for services furnished to Medicare beneficiaries must enroll in Medicare **in order to submit claims** on behalf of such beneficiaries. If they do not enroll, they cannot receive payments for Medicare covered services.

Medicare Program Integrity Manual, Ch. 10, Healthcare Provider/Supplier Enrollment, § 1 (emphasis added). Nothing in these instructions suggests that under arrangements vendors must be enrolled in the Medicare program.

3.7 Coverage for Hospital Outpatient Services "Incident to" a Physician's Service and the Location of the Service

A. When CMS created the provider-based regulations in 2000, it also amended the coverage regulation for hospital outpatient services "incident to" a physician's services. As amended in 2000, the regulation stated that such services are covered only if they are furnished "in the hospital or at a location . . . that CMS designates as a department of a provider under [42 C.F.R.] § 413.65. . . ."

1. The preamble language associated with this amendment was silent on what was intended or why the agency thought this amendment was needed. *See* 63 Fed. Reg. 47552 (Sept. 8, 1998) (proposed rule) and 65 Fed. Reg. at 18524-25 (Apr. 7, 2000) (final rule), both of which address physician supervision only. Indeed, there is a legitimate question as to whether the "basis and purpose"

statement was sufficient to meet the rulemaking requirements under the Administrative Procedure.

2. Notwithstanding the literal wording of the regulation, CMS did not amend its manual setting forth coverage policy which clearly stated that there is coverage as a hospital outpatient service for "incident to" services furnished off the hospital's premises. Benefit Pol. Man. (CMS Pub. 100-02), Chpt. 6, § 20.4.1. Indeed, that Manual continues, as of when this is written to provide for such coverage.

3. In addition, several lawyers have reported receiving CMS Regional Office approval of under arrangements transactions in which services could only be covered under the "incident to" benefit were furnished by a vendor in off-premises locations.

B. 2007 OPPS Rulemaking

1. CMS amended the wording of 42 C.F.R. § 410.27(a) to read:

> Part B pays for hospital services and supplies furnished incident to a physician service to outpatients … if (1) They are furnished … (iii) In the hospital or at a department of a provider, as defined in § 413.65(a)(2) of this subchapter, that has provider-based status in relation to a hospital under § 413.65 of this subchapter.

CMS explained that the amendment was to make the rule consistent with a 2002 regulatory amendment whereby hospitals no longer had to have affirmative CMS approval for a provider-based site. CMS did not suggest that there was any ambiguity in its prior rule. 72 Fed. Reg. 66580, 66817-18 (Nov. 27, 2007).

2. In preamble language, CMS made clear that it outpatient hospital services covered under the "incident to" provision of the coverage rules had to be furnished in hospital space, including provider-based space:

> In the proposed rule, we also reminded hospitals of the requirements of § 410.27 concerning services and supplies furnished incident to a physician's service to hospital outpatients. Section 410.27 applies to all "incident to" services covered under section 1861(s)(2)(B) of the Act. This provision does not apply to services covered under other benefit categories ….
>
> As discussed in the CY2008 OPPS/ASC proposed rule, we recognize that hospitals consider a variety of business

> models in their efforts to supply efficient and high quality health care services to Medicare beneficiaries and the general public, and we support such efforts to the extent that they comply with all applicable laws and regulations, including, but not limited to, the Stark law and other anti-kickback laws. Recently, we have received an increasing number of questions about a number of hypothetical business arrangements between hospitals and other entities, including ASCs. We remind hospitals contemplating various business models that involved "incident to" services provided to hospital outpatients to consider the requirements of § 410.27. Under § 410.27, "incident to" services that are provided to hospital outpatients must be furnished in the hospital or at a department of a provider ....

Id. at 66818, col. 1-2. *See also* Med. Ben. Pol. Manu. (CMS Pub. No. 100-02), Chp[at. 6, § 20.5.1 (as amended by Trans. 82, Feb. 8, 2008).

3.8 Dealing with Coverage Requirement that "Incident to" Services Be Furnished in the Hospital or in a Provider-Based Department

A. What Is the Hospital?—No part of hospital premises is inherently hospital space; all portions of the hospital must meet the provider-based criteria.

B. How can a hospital assure that a service will be deemed to have been furnished by a provider-based department?

1. Meet *all* of the requirements for provider-based status set forth at 42 C.F.R. § 413.65, including: ownership of the business enterprise (with the exception of joint ventures located on the main campus); administrative integration; clinical integration; financial integration; holding out to the public as part of the hospital; and meeting the obligations of provider-based status.

2. Medicare policy bars provider-based status if all of the services at a "facility or organization" are furnished under arrangements. 42 C.F.R. § 413.65(i).

> A facility or organization may not quality for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

C. What is a "facility or organization"? CMS policy seems to focus on physical location. In Transmittal A-03-030 (Apr. 18, 2003), CMS said that the provider-based rules "do not apply to specific services; rather these rules are site specific." In the same transmittal, CMS said that a main provider submitting an attestation for provider-based status "must

enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus). CMS added that "a facility may be an entire building, two or more buildings, or defined areas within a building," and says that the "provider-based rules are site specific."

D. CMS will not consider a "facility or organization" that furnishes "all" services under arrangements as provider-based. What does "all" mean?

1. CMS has, in a preamble, referred to "all or virtually all" services in characterizing this regulation. 67 Fed. Reg. 49982, 50091 (Aug. 1, 2002). The lower the volume of services at a facility or organization furnished directly by a provider, the greater the desirability of obtaining CMS approval through the provider-based attestation process.

2. Must, or should, the services furnished directly by the provider at the "facility or organization" be clinically related to the services furnished under arrangements?

3.9 Radiation Therapy Services—Basis for Coverage

A. There is a separate basis of coverage for radiation therapy services, 42 C.F.R. § 410.35. Accordingly, these services when billed by a hospital are not covered under the "incident to" benefit, and thus, should not be subject to the limitations on the location at which arranged for services can be furnished. The CMS Chicago Regional Office, however, has taken the initial position that radiation therapy services may not be furnished under arrangements at an off-site location.

B. Affected services include linear accelerator services and cyberknife.

3.10 Provider-Based Joint Venture—A Solution for a Vendor to Bear Business Risk and Enjoy Investment Returns without Losing Medicare Coverage for "Incident to" Services?

A. In response to comments, CMS amended its regulations to permit providers to operate a joint venture as a provider-based site so long as the site is located on the campus of a provider that is a part owner, but the site must meet all the provider-based requirements for an on-campus department. 42 C.F.R. § 413.65(f).

B. There is considerable uncertainty what this really means. As CMS makes clear, the services furnished in the provider-based joint venture site must be "billed using the provider number of the provider whose campus on which the facility is located." 67 Fed. Reg. at 50090, col. 1 (Aug. 1, 2000). Since the joint venture is neither billing nor collecting the revenue (at least from governmental payers), a mechanism is needed to move collections from the provider to the joint venture – usually a contract in exchange for services. Thus, it is not clear what is the distinction between a provider-based joint venture and a provider contracting with a related

organization for management of a provider department. Presumably with a joint venture, the party with whom the hospital contracts has made a capital investment and has a part interest in the assets of the department, and also has an interest in net income.

C. A joint venture can be treated as provider-based only if it meets all the requirements for a provider-based site including clinical integration, financial integration, and being held out to the public as part of the provider. The financial integration standard requires that the:

> financial operations of the [site] are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the [site]. The costs of [the site] that is a hospital department are reported in a cost center of the provider . . . and the financial status of any provider-based [site] is incorporated and readily identified in the main provider's trial balance.

42 C.F.R. § 413.65(d)(3). An accountant's advice is necessary to determine if this standard could be met by a joint venture operating on the provider's premises as a provider-based department.

D. Notwithstanding the uncertainties in CMS's policy with respect to provider-bases joint ventures, this may be one mechanism to use something close to an under arrangements model for certain services covered as hospital outpatient services "incident to" a physician's service.

IV. STARK LAW

4.1 Introduction

A. The Federal physician self-referral law (the "Stark Law") (42 U.S.C. § 1395nn) prohibits a physician from referring Medicare patients to entities with which the physician has a "financial relationship" for the provision of "designated health services" ("DHS") and prohibits entities from billing for DHS furnished pursuant to a prohibited referral. Under the Stark Law, a "financial relationship" can consist of a compensation arrangement, an ownership interest, or an investment interest. A "compensation arrangement" is defined as any arrangement involving any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) between a physician (or an immediate family member of a physician) and an entity. 42 U.S.C. § 1395nn(h)(1). "Designated health services" include: clinical laboratory services; physical and occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial topography scans, and ultrasound services; radiation therapy services; durable medical equipment; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health

services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6).

B. Regulations implementing the Stark Law (as it initially applied to clinical laboratory services) were issued by the Centers for Medicare and Medicaid Services ("CMS"; at the time of issuance "HCFA") in 1995 (the "Stark I Final Regulations"). 60 Fed. Reg. 41914 (Aug. 14, 1995). Proposed Regulations implementing the Stark Law (as expanded to include all DHS) were issued by HCFA in 1998 (the "Stark II Proposed Regulations"). 63 Fed. Reg. 1659 (Jan. 9, 1998). Additional regulations were issued in 2001, in the phase I final Stark II regulations (the "Phase I Regulations"). 66 Fed. Reg. 856 (Jan. 4, 2001). The second phase of the Stark Law regulations were released in the form of an interim final rule and became effective on July 26, 2004 ("Phase II Regulations"). 69 Fed. Reg. 16054 (March 26. 2004). As further discussed below, final regulations were released and became effective on December 4, 2007 (the "Phase III Regulations"). 72 Fed. Reg. 51012 (Sept. 5, 2007). Unlike the Anti-Kickback Statute, the Stark Law does not contain an intent requirement. Therefore, if an arrangement implicates the Stark Law, physician referrals are prohibited unless the arrangement complies with the requirements of an exception.

C. The Stark Law will be implicated in any under arrangements relationship of a hospital if the provider of the under arrangements services is a physician (or immediate family member) or physician group, or if a physician (or immediate family member) has an ownership or investment in, or compensation relationship with, the provider.

4.2 Definition of "Entity"

A. Stark Law at present does not expressly prohibit physician ownership in an entity that provides services to a hospital under arrangements, so long as the hospital/entity/physician compensation arrangement meets an exception. CMS initially took the position in the 1998 Stark II Proposed Regulations that both the hospital purchasing the under arrangements service and the provider of the service were "entities" subject to the Stark Law prohibition. 63 Fed. Reg. 1659, 1706 (Jan. 9, 1998). In the Phase I Regulations, however, CMS determined to treat under arrangements relationships between hospitals and physician-owned service providers as compensation relationships, rather than to prohibit physician ownership of such service providers. In doing so, CMS stated, "We will, however, monitor these arrangements and may reconsider our decision if it appears that the arrangements are abused. We also caution physician groups and hospitals that these arrangements remain subject to the Federal anti-kickback statute." 66 Fed. Reg. 856, 942 (Jan. 4, 2001).

B. In the 2008 Medicare physician fee schedule proposed rule ("MPFS Proposed Rule"), CMS proposed revising the definition of "entity" to include both the party that performs the designated health service and the hospital that submits claims to Medicare for designated health services furnished under arrangements. 72 Fed. Reg. 38122 (July 12, 2007). Specifically, CMS proposed revisions to the definition of "entity" in 42 C.F.R. § 411.351 to state that an entity is considered to be furnishing a designated health service if it "has performed the DHS" or "[p]resented a claim or caused a claim to be presented for Medicare benefits for the DHS."

1. In the preamble discussion in the MPFS Proposed Rule, CMS expressed a number of concerns regarding services furnished by hospitals under arrangements with physician-owned entities. It indicated it was particularly concerned about hospital outpatient services reimbursed on a per-service basis, such as imaging services, and understood there are hospital-physician ventures providing imaging services under arrangements that were previously provided directly by the hospital. CMS stated that there often appears to be no legitimate reason for such arranged services, other than to allow the referring physicians "to make money on referrals." 72 Fed. Reg. 38122, 38186 (July 12, 2007).

2. CMS also expressed concern about services being furnished under arrangements in a less medically-intensive setting than a hospital but billed at hospital rates. CMS indicated its belief that specialists set up joint ventures, often with hospital partners, that own an entity such as an IDTF or ASC and provide services under arrangements to the hospital. Again, CMS indicated that such arrangements "may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries." 72 Fed. Reg. 38122, 38186 (July 12, 2007).

3. The revision proposed by CMS would jeopardize all under arrangements relationships with physician-owned entities, regardless of whether they have the abusive characteristics CMS notes as the cause for its concerns. If the proposed rule is adopted, physicians will be prohibited from referring patients for DHS provided by entities they own to a hospital under arrangements except in the limited circumstances where an equity joint venture with the physicians would be feasible – for example, an under arrangements relationship with a rural provider (in which case the physicians' ownership of the provider would meet the rural provider exception under 42 C.F.R. § 411.356(c) and the relationship between the hospital and the rural provider/physician

owners would need to be analyzed under the definition and exception for indirect compensation arrangements).

4. It is not entirely clear how the revisions proposed in the MPFS Proposed Rule would affect ventures for services, such as most cardiac catheterization services, that do not constitute DHS in their own right but are DHS when provided by a hospital because they then constitute hospital services. CMS' reference to ASCs in the preamble, as noted above, may indicate that the intent is to cover such arrangements within the scope of the prohibition.

5. Application of the proposed revisions would also result in questions about when an entity "has performed" or causes a claim to be presented for DHS. What if an entity provides space, management services, equipment, supplies and/or staffing services? How many of these components taken together will constitute performance of the DHS?

C. In the preamble to the MPFS Proposed Rule, CMS also solicits comments on MedPAC's recommended approach of expanding the definition of physician ownership to encompass any entity "that derives a substantial proportion of its revenue from a provider of designated health services." 72 Fed. Reg. 38122, 38187 (July 12, 2007), quoting from the Medicare Payment Advisory Commission March 2005 Report to Congress. CMS indicates that it agrees with MedPAC's concerns about referring physician ownership of leasing, staffing and similar entities that furnish items and services to entities furnishing DHS. Thus, although stating that it believes the approach discussed above is sufficient, CMS solicited comments on whether to implement the MedPAC approach instead of, or in addition to, CMS' proposed approach, and indicates it is particularly interested in comments on what should constitute a "substantial" proportion of revenue. Adoption of the MEdPAC approach would have far-reaching effects on contractual relationships between physicians and DHS entities.

D. CMS did not adopt the changes discussed above in the final physician fee schedule rule for 2008 ("MPFS Final Rule"), but indicated that it intended to publish a final rule addressing these proposals, without the need for new proposals or additional public comment. 72 Fed. Reg. 66222, 66306 (Nov. 27, 2007).

4.3 "Indirect Compensation" - Generally

A. Assuming an entity with physician owners that provides services to a hospital under arrangements is not a "physician organization" (as discussed further below), the hospital's relationship with the physicians

will be analyzed under current law as an indirect compensation relationship.

B. An indirect compensation arrangement exists if: (a) there exists between the referring physician and the designated health services entity an unbroken chain of persons or entities that have financial relationships between them; (b) the aggregate compensation received by the referring physician varies with, or takes into account, the volume or value of referrals or other business generated by the physician for the DHS entity; and (c) the designated health services entity has actual knowledge that the aggregate compensation received by the referring physician varies with, or takes into account, the volume or value or referrals or other business, or acts in reckless disregard or deliberate ignorance of the existence of such relationship. 42 C.F.R. § 411.354(c)(2).

1. The compensation relationship closest to the individual physicians is the financial relationship to analyze for purposes of applying the indirect compensation definition. In assessing a relationship with a supplier owned in part by physicians, the financial relationship between the hospital and the supplier must be analyzed.

C. CMS has expressed concern about whether parties are reading the definition of "indirect compensation" too narrowly. In the preamble to the proposed rule addressing changes to the inpatient prospective payment system for fiscal year 2009, 73 Fed. Reg. 23527 (April 30, 2008) (the "IPPS Proposed Rule"), CMS indicated that the second prong of the test for an indirect compensation relationship may be met in a "wide range of circumstances, including, without limitation, arrangements involving: variable, per-click or percentage-based compensation; exclusive contracts; inflated fixed payments; or explicit or implicit tying of compensation to other referrals." 73 Fed. Reg. 23527, 23687 (April 30, 2008). CMS further indicated it may provide additional guidance on the definition of "indirect compensation" in the FY 2009 IPPS final rule, and solicited comments on ways to ensure that "the full range of potentially abusive arrangements" are addressed.

1. CMS had previously indicated, in the preamble discussion of the Phase II Regulations, that "[s]ince time-based or unit-of-service based compensation will always vary with the volume or value of services when considered in the aggregate, these compensation arrangements can constitute 'indirect compensation arrangements' under § 411.354(c)(2), even if the individual time or unit-of-service based compensation is fair market value and otherwise complies with the language of § 411.354(d)(2) and § 411.354(d)(3)." 69 Fed. Reg. 16054, 16069 (March 26, 2004).

D. If an indirect compensation arrangement is found to exist, the parties will need to structure the relationship to meet the applicable exception. The exception for indirect compensation arrangements requires compliance with the following conditions: (a) the compensation received by the referring physician (or an immediate family member) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnished the designated health service; (b) the compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment arrangement in which case the arrangement need not be in writing but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer; and (c) the compensation arrangement does not violate the Anti-Kickback Statute or any federal or state law/regulation governing billing or claims submission. 42 C.F.R. § 411.357(p).

4.4 "Indirect Compensation" – Physician "Stand in the Shoes"

A. Under current law, whether a compensation arrangement between a hospital and a physician-owned under arrangements service provider would be analyzed under the Stark Law as an indirect compensation relationship or as a direct compensation relationship will depend on application of the new "stand in the shoes" concept. Under 42 C.F.R. § 411.354(c), as amended by the Phase III Regulations, physicians "stand in the shoes" of their physician organizations such that a compensation relationship with a physician organization is considered a direct compensation arrangement with its physicians. In this case, "the 'parties' to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians)." 42 C.F.R. § 411.354(c)(3)(i). See amended version of 42 C.F.R; § 411.354(c) in 72 Fed. Reg. 51012, 51087, and related preamble discussions at 72 Fed. Reg. 51012, 51027-29, 51061-63 (Sept. 5, 2007).

1. A "physician organization" is defined in 42 C.F.R. § 411.351, as amended by the Phase III Regulations, to consist of a physician, physician practice or group practice (that complies with the requirements of a "group practice" under 42 C.F.R. § 411.352). After publication of the Phase III Regulations, CMS posted "Frequently Asked Questions" on its web site that addressed a number of questions relating to the definition of "physician organization." Posted at http://www.cms.hhs.gov/PhysicianSelfReferral/05a_FAQs.asp#TopOfPage. Included in this posting is a response defining "physician practice" as "a medical practice comprised of two or

more physicians organized to provide patient care services (regardless of its legal form or ownership)," and responses clarifying that none of the following is a "physician organization": a hospital that directly employs or contracts with physicians; a staffing company that does not directly provide and bill for patient services; a federally qualified health center; a single legal entity that encompasses both a faculty practice plan and a medical school or hospital; and a medical school that employs physicians.

B. Arrangements complying with the indirect compensation arrangement exception that were entered into prior to the publication date of the Phase III Regulations may continue to rely upon that exception as if the new "stand in the shoes" standard was not adopted for the duration of the original term or the current renewal term of the arrangement. See amended version of 42 C.F.R; § 411.354(c)(3)(ii) in 72 Fed. Reg. 51012, 51083 (Sept. 5, 2007). Thereafter, these grandfathered arrangements must be restructured as necessary to comply with a direct compensation arrangement exception. Aside from these arrangements, the indirect compensation analysis continues to apply to arrangements involving an intervening entity other than a physician organization, or involving more than one intervening entity.

1. The Frequently Asked Questions posted by CMS also address this grandfathering provision. The response to Question #8886 indicates that grandfathering does not apply to an arrangement that did not meet the definition of "indirect compensation arrangement" but would have satisfied the requirements of the exception for indirect compensation arrangements had it been applicable. Only arrangements that both met the definition of "indirect compensation arrangement" and satisfied the requirements of the exception are eligible for grandfathering.

C. CMS published a final rule in November 2007 delaying the effectiveness of the "stand in the shoes" provisions until December 4, 2008, for academic medical centers and integrated 501(c)(3) health care systems. 72 Fed. Reg. 61461 (Nov. 15, 2007). This delay, which was in response to concerns raised about the ability of health systems to provide "mission support payments" to their affiliated physician organizations, applies only to relationships between (a) a faculty practice plan and another component of an academic medical center, and (b) an affiliated DHS entity and affiliated physician practice in the same integrated section 501(c)(3) health care system.

D. CMS further addresses this "stand in the shoes" concept in the IPPS Proposed Rule. In addition to discussing interaction between the physician "stand in the shoes" concept and the entity "stand in the shoes"

concept proposed in that rule (as further discussed below), CMS proposed new regulatory language and sought comments concerning alternative approaches for addressing mission support payments. See proposed revision of definition of "physician organization" and proposed revision of 42 C.F.R. § 411.354(c) in 73 Fed. Reg. 23527, 23704, and related preamble discussions at 73 Fed. Reg. 23527, 23685-88 (April 30, 2008).

1. Under the regulatory language proposed in the IPPS Proposed Rule, a physician would stand in the shoes of his/her physician organization unless his/her only compensation relationship with the physician organization is one that meets the exception for employment, personal services arrangements or fair market value compensation. It also provides the stand in the shoes concept does not apply to arrangements that satisfy the academic medical center exception or to arrangements between a component of an academic medical center and a physician organization for provision to the center of only those services required to satisfy the center's obligations under the Medicare GME rules.

E. The physician "stand in the shoes" principle will affect hospital under arrangements transactions if the provider of the under arrangements services is a physician organization. In those circumstances, the compensation relationship between the hospital and the under arrangements provider will need to meet an exception for a direct compensation relationship – most likely, the personal services arrangements or fair market value exception – rather than being subject to analysis under indirect compensation principles.

4.5 "Indirect Compensation" - DHS Entity "Stand in the Shoes"

A. In the preamble to the MPFS Proposed Rule, CMS proposed that "where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls." 72 Fed. Reg. 38122, 38184 (July 12, 2007).

B. CMS took up this issue again in the IPPS Proposed Rule. See proposed revisions to 42 C.F.R. § 411.354(a) in 73 Fed. Reg. 23527, 23704, and related preamble discussion at 73 Fed. Reg. 23527, 23688-90 (April 30, 2008). Under the proposed regulatory text, a DHS entity would stand in the shoes of an organization in which it has a 100% ownership interest (regardless of whether that organization itself provides any DHS). CMS states that an organization in any legal form is covered by this proposal, including LLCs, partnerships and corporations, whether for-profit or nonprofit. In the preamble to the IPPS Proposed Rule, CMS requests comments on whether ownership of less than 100% should apply and if so,

what amount of ownership should be sufficient. CMS also requests comments on whether a control test should be used – under which, for example, "an entity would stand in the shoes of a nonprofit organization of which it is the sole member" – and if so, what level of control should be sufficient. CMS indicates that for this purpose control means "the power, directly or indirectly, significantly to influence or direct the actions or policies of the organization." 73 Fed. Reg. 23527, 23689 (April 30, 2008).

C. Query how application of the alternative ownership or control test would affect analysis of a hospital-physician joint venture where the hospital has a controlling interest or otherwise exercises significant control.

D. In the preamble to the IPPS Proposed Rule, CMS also proposed conventions for applying the physician and entity stand in the shoes principles when both are potentially applicable. CMS indicated that regulatory text addressing these conventions would be included at such time as the stand in the shoes provisions are finalized.

4.6 Per Unit and Percentage Payment Arrangements

A. In the MPFS Proposed Rule, CMS proposed revisions to 42 C.F.R. §§ 411.357(a)(5) and 411.357(b)(4) that would prohibit per unit-of-service rental charges to the extent that they reflect services provided to patients referred by the lessor to the lessee. Proposed regulations in 72 Fed. Reg. 38122, 38224; discussed in preamble at 72 Fed. Reg. 38122, 38182-83 (July 12, 2007).

1. CMS also requested comments on whether time-based and per-unit-of-service charges should be prohibited when they reflect services to patients sent to a physician lessee by the lessor.

2. In the preamble, CMS noted that it was concerned "about arrangements where the physician is the lessee and rents space or equipment from a hospital or other DHS entity on a per-click basis. For example, if a physician rents an MRI machine from a hospital only when the physician refers a patient for an MRI and then provides the facility portion of the MRI service under arrangements with the hospital . . . ." Presumably, in considering prohibition of per unit compensation from a physician lessee, CMS intends to address such an under arrangements transaction.

3. As proposed, these changes would affect only the direct compensation relationship exceptions for space and equipment leases. Thus, indirect compensation relationships would not be affected by these changes.

B. In the MPFS Proposed Rule, CMS also proposed to revise 42 C.F.R. § 411.354(d) to specify that percentage-based compensation is considered not to be "set in advance," with the exception of "compensation based on revenues directly resulting from personally performed physician services." Proposed revision at 72 Fed. Reg. 38122, 38224; discussed in preamble at 72 Fed. Reg. 38122. 38184 (July 12, 2007).

1. Under the currently effective version of 42 C.F.R. § 411.354(d)(1), percentage compensation is considered set in advance if the formula is set forth in sufficient detail to be objectively verifiable, and does not change in any manner that reflects the volume or value of referrals or other business generated between the parties. Percentage compensation is not, however, included in the provisions of 42 C.F.R. § 411.354(d)(2) and (3), which deem certain unit-based compensation arrangements not to take into account the volume or value of referrals or other business generated. In the preamble to the Phase III Regulations, CMS indicated it was not persuaded that percentage compensation should be included within the scope of 42 C.F.R. § 411.354(d)(2) and (3). 72 Fed. Reg. 51012, 51030-31 (Sept. 5, 2007).

2. In the preamble to the Phase III Regulations, CMS also discussed use of percentage of collections payment in a contract for outpatient radiology services between a hospital and a joint venture owned by the hospital and physicians. CMS indicated that the arrangement would create an indirect compensation relationship, and is not affected by the provisions of 42 C.F.R. § 411.354(d)(1), because those provisions pertain only to the "set in advance" requirement, which is not a requirement of the indirect compensation arrangements exception. CMS further indicated that the arrangement would not meet the exception for indirect compensation arrangements if "the return to the physician from the radiology joint venture takes into account in any manner the physician's referrals to the hospital (whether or not these referrals involve services provided by the joint venture)." Last, CMS cautioned that to meet the exception, the compensation actually received under the arrangement must be fair market value for items and services provided, and that depending on how collections progress, a percentage of collections may not meet this test. 72 Fed. Reg. . 51012, 51062-63 (Sept. 5, 2007).

C. CMS did not adopt the changes discussed above in the MPFS Final Rule, but indicated that it intended to publish a final rule addressing these proposals, without the need for new proposals or additional public comment. 72 Fed. Reg. 66222, 66306 (Nov. 27, 2007).

V. FEDERAL ANTI-KICKBACK STATUTE

5.1 Introduction

The Anti-Kickback Statute imposes criminal and civil money penalties on any entity that knowingly or willfully pays or offers to pay, or solicits or receives any remuneration directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral of patients for any item or service which is covered in whole or in part by a federal health care program. 42 U.S.C. § 1320a-7b. The Anti-Kickback Statute also prohibits arranging for or recommending the purchase of goods or services for which payment may be made in whole or in part under a federal health care program in exchange for remuneration. The Anti-Kickback Statute is an intent-driven statute (*e.g.* a violation requires proof of illegal intent to induce referrals). Thus, analysis of a proposed venture often necessitates a review of all of the facts and circumstances, and design of safeguards to reduce the risk of a violation. Concerns and potential safeguards applicable to under arrangements ventures are discussed below. In addition, it is often useful to consider the questions that would need to be answered in submitting an advisory opinion request to the OIG. See the suggested questions in Attachment A posted at http://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm.

5.2 Concerns Expressed About Under Arrangements Transactions

CMS has indicated that under arrangements relationships raise "significant issues" under the Anti-Kickback Statute. Particular skepticism is expressed with respect to under arrangements transactions designed to permit physician groups to provide services under arrangements that the hospital previously provided directly, "especially when they involve particularly lucrative lines of business." 66 Fed. Reg. 856, 942 (Jan. 4, 2001). At the same time, CMS recognized that in some circumstances, such as when physicians provide under arrangements services in physician-owned facilities primarily to their own patients, the under arrangements relationship can "avoid unnecessary duplication of costs and underutilization of expensive equipment." Recently, as noted above, CMS has expressed concern in the MPFS Proposed Rule without acknowledging that under arrangements relationships can be beneficial in some circumstances. Specifically, CMS stated that under arrangements ventures involving services previously provided directly by hospitals appear to have no purpose "other than to allow referring physicians to make money on referrals for separately payable services," and that ventures between specialists and hospitals that own an entity such as an IDTF or ASC and provide services under arrangements to the hospital also "may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries." 72 Fed. Reg. 38122, 38186 (July 12, 2007).

5.3 Terms of Services Arrangement

A. The relationship between the hospital and the under arrangements provider theoretically could be structured to meet the "safe harbor" for personal services and management contracts. This safe harbor requires:

- The agreement is set out in writing and signed by the parties;

- The agreement covers all of the services for the term of the agreement and specifies the services to be provided;

- If the agreement is intended to provide for services on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;

- The term of the agreement is for not less than one year;

- The aggregate compensation paid over the term of the agreement is set in advance;

- The aggregate compensation paid over the term of the agreement is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties;

- The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and

- The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services. 42 C.F.R. § 1001.952(d).

B. The protection of a safe harbor is available only if all of its elements are met, but arrangements outside a safe harbor are not per se illegal, and will be reviewed on a case-by-case basis, in light of all the relevant facts and circumstances. The personal services safe harbor does not permit payment that fluctuates based on the extent of services required, making it unlikely to be a feasible option for under arrangements relationships in which the parties are unlikely to be able to predict in advance the amount of services that will be needed over the course of a year. However, an approach to mitigate risk under the Anti-Kickback Statute is to structure the relationship to comply as closely as possible to the safe harbor.

C. The OIG has consistently declined to provide safe harbor protection to per use fee arrangements. See, for example, 56 Fed. Reg. 35952 (July 29, 1991) available at http://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm., 64 Fed. Reg. 63504, 63526 (Nov. 19, 1999), and Appendix G to the OIG Semiannual Report to Congress for April-September 2002. The OIG has also made clear in advisory opinions that such arrangements are "disfavored," because of concerns that they promote overutilization. See, for example, OIG Advisory Opinion 03-8 (April 3, 2003); OIG Advisory

Opinion 99-12, fn 4 (Nov. 23, 1999). The key issue is whether the total amount paid under the per use fee arrangement will vary based on referrals generated by the recipient of the fee. If so, the fee may provide an inappropriate incentive for referrals.

5.4 Equity Joint Venture Analysis

A. If a hospital and physicians form a joint venture that will provide under arrangements services, the small entity investment safe harbor will also be relevant. That safe harbor requires:

- No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (the "40% Investment Test");

- The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors;

- The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity;

- There is no requirement that an investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor;

- The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to investors differently than to non-investors;

- No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors (the "40% Revenue Test");

- The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest; and

- The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any preoperational services rendered) of that investor. 42 C.F.R. § 1001.952(a)(2).

In analyzing a joint venture formed to provide services under arrangements to a hospital, both the investing physicians and the hospital would be considered referral sources for purposes of applying this safe harbor, making satisfaction of the 40% Investment Test and 40% Revenue Test unlikely. Thus, as in many other cases, safe harbor protection is unlikely to be feasible.

B. In addition to the requirements of the safe harbor itself, consideration should be given to the OIG's 1989 Fraud Alert concerning joint ventures and discussion of joint ventures in the 2005 Supplemental Compliance Program Guidance for Hospitals (the "Supplemental Guidance"). 70 Fed. Reg. 4858, 4865-66 (Jan. 27, 2005).

1. The OIG's concerns about joint ventures with physicians were expressed early, in its 1989 OIG Special Fraud Alert, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html. The OIG indicated it views as suspect any joint venture in which physicians are investors and are in a position to refer to the joint venture because such an ownership structure can constitute evidence of intent on the part of those involved in the joint venture to provide remuneration (in the form of profit distributions) to the physician investors in exchange for their referrals. The OIG particularly noted the following as indicia of a potentially fraudulent joint venture:

    - Investors are chosen because they are in a position to make referrals

    - Greater investment opportunity is offered to larger referral sources

    - Investors are actively encouraged to refer and/or required to divest their interests if they do not refer

- Investors are required to divest if they no longer practice in the venture's service area

- Transferability of investments is restricted

- Investor referrals are tracked and this information is provided to the investors

- The joint venture entity could be characterized as a "shell" – it relies on one of the investors to obtain the infrastructure and services necessary for its business

- Investors receive a disproportionately large return

- Only nominal investments are required

- Cash for the investment is loaned by the venture or by other investors

2. The Supplemental Guidance discusses steps the OIG recommends hospital undertake in analyzing potential relationships with referral sources, including equity joint ventures, and echoes the concerns expressed in 1989. It indicates the following factors should be considered in analyzing equity joint ventures:

   - How the joint venture participants are selected and retained. Indicia suggesting an improper nexus with referrals include:
     - A substantial number of the investors are in a position to refer to the venture or to other investors
     - More favorable opportunities are offered to those expected to make a large number of referrals
     - Investors are actively encouraged to refer
     - Investors are encouraged or required to divest if they do not refer
     - Referrals are tracked and information provided to investors
     - Investments are nontransferable or subject to restrictions on transfer that are related to referrals

   - How the joint venture is structured. A joint venture is suspect if one of the investors is already engaged in the line of business and provides the equipment, supplies and/or services necessary for operation of the venture. In that circumstance, the OIG is concerned that the other venture partner is merely contributing its referral base.

- How investments are financed and profits distributed. The following are noted as suspect:
  - Nominal capital contributions
  - Disproportionately large returns relative to the capital invested
  - Funds for investment are borrowed from the venture or another participant, then repaid from distributions, thus eliminating any true cash contribution
  - Extraordinary returns are paid in comparison with the risk involved
  - A substantial part of the venture's revenues are derived from investor referrals.

3. The OIG further recommends in the Supplemental Guidance that hospitals participating in joint ventures should take the following steps to reduce the risk of abuse:

- Bar physicians employed by the hospital and its affiliates from referring to the venture
- Take steps to assure medical staff members and other affiliated physicians are not encouraged to refer to the venture
- Notify physicians annually of policies concerning the foregoing
- Refrain from tracking referrals attributable to particular sources
- Ensure physician compensation is not tied to referrals to the venture
- Disclose all financial interests to patients
- Require other participants in the venture to adopt similar steps.

5.5 Contractual Joint Venture Analysis

A. The OIG issued a Special Advisory Bulletin on Contractual Joint Ventures on April 23, 2003 (the "Advisory Bulletin"), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf In the Advisory Bulletin, the OIG focused on arrangements where a health care provider in one line of business (the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (the "Supplier") to provide the related item or service to the Owner's existing patient population, including Medicare and Medicaid patients. The Supplier not only manages the line of business for the Owner, but may also supply it with inventory, employees, space,

billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals. The OIG identifies the following factors as being indicative of a questionable contractual joint venture arrangement:

- New Line of Business. An Owner is expanding into a new line of business which is dependent on referrals from, or other business generated by, the Owner's existing patient base;

- Captive Referral Base. The Owner has a captive referral base and the newly-created business predominately or exclusively services the existing patient base;

- Little or No Bona Fide Business Risk. The arrangement results in little or no bona fide business risk to the Owner and the Owner's primary contribution is referrals;

- Status of the Supplier. The Supplier is an individual or entity that would normally be a competitor of the Owner's new line of business but for the contractual relationship;

- Scope of Services Provided by the Supplier. The Supplier provides all or many of the key services related to the operation of the business (e.g. management, billing, equipment, personnel, office space, supplies);

- Remuneration. As a practical effect the arrangement gives the Owner the opportunity to bill for business otherwise provided by the Supplier. The remuneration from the venture to the Owner (i.e. the profits of the venture) takes into account the value or volume of the business the Owner generates; and

- Exclusivity. The arrangement is exclusive in nature (e.g. contains non-compete clauses) and bars the Owner from providing items or services to any patients other than those coming from the Owner and/or barring the Supplier from providing services in its own right to the Owner's patients.

The OIG emphasized in the Advisory Bulletin that the foregoing factors are not exhaustive and arrangements involving the delegation of fewer than substantially all services, or delegation to a party not otherwise in a position to bill for the identical services, may also give rise to concerns under the Anti-Kickback Statute, depending on the circumstances. Also see OIG Advisory Opinion 04-17 (Dec. 10, 2004).

B. The Supplemental Guidance mentions under arrangements relationships in its discussion of contractual joint ventures, stating that, standing alone, they "do not fall within the scope of problematic contractual joint ventures described in the Special Fraud Alert; however, these relationships will violate the anti-kickback statute if remuneration is purposefully offered or paid to induce referrals (*e.g.,* paying above-market rates for the services to influence referrals or otherwise tying the arrangements to referrals in any manner). These 'under arrangements' relationships should be structured, when possible, to fit within an anti-kickback safe harbor." 70 Fed. Reg. 4858, 4866 fn. 49 (Jan. 31, 2005). As noted above, the inability to predict the extent of services required makes satisfaction of a safe harbor unlikely.

C. The risk factors for contractual joint ventures are worth consideration in analyzing an under arrangements venture. To the greater extent the hospital provides infrastructure for the venture – i.e., the hospital plays the role of Owner and the under arrangements service provider/physician owners have the role of Supplier as described above – the more suspect the relationship will be.

5.6 Facts and Circumstances Analysis

Again, all of the facts and circumstances of the proposed arrangement must be analyzed to assess risk under the Anti-Kickback Statute. Of course, the purpose of the parties in pursuing the venture is key. Following are some of the factors to be considered.

A. Favorable and Mitigating Factors

- The under arrangement relationship provides hospital patients with access to specialized services not otherwise available
- The transaction otherwise provides services that meet a need the hospital is not currently meeting for other reasons, such as lack of sufficient capacity
- The arrangement enables provision of improved equipment and/or quality of care
- The transaction results in enhanced patient convenience or access – for example, by expanding available locations for services
- The transaction increases the ability of the hospital to provide services in medically underserved areas or to medically underserved populations
- The transaction results in the ability to provide the service at a lower cost – to the hospital and/or patients

- The physician owners of the service provider are personally involved in the provision of the services
- The physician owners of the service provider take on significant and bona fide business risk and clearly contribute something to the venture other than referrals
- Significant investment in the service provider is required and all investors pay fair market value for their interests
- The fair market value of the compensation for the under arrangements services is established, and possibly confirmed by an independent expert opinion
- The amount received by the physicians does not vary in a manner that relates to the extent of their referrals
- Physicians disclose their ownership interest to patients
- Application of the hospital's and venture's quality assurance and utilization review program reduces the risk of referrals for inappropriate or medically unnecessary services
- The terms of the arrangement are set forth in a written agreement and the other criteria of the services safe harbor criteria are met to the extent feasible

B. Risk Factors

- The hospital previously provided the service directly
- Reimbursement for the service is particularly lucrative
- Investment terms are offered contrary to the safe harbor and OIG guidance on equity ventures discussed above - investors are selected based on referrals, loans, requirements to divest, etc.
- The hospital provides significant infrastructure and/or services to the venture - the arrangement has suspect characteristics of a contractual joint venture discussed above

VI. HYPOTHETICAL

Cardiac Catheterization Services, LLC (CCS) is a limited liability company. The majority is owned by 5 cardiologists, but there are nonphysician investors as well. CCS operates a cardiac catheterization lab located in a medical office building adjacent to a hospital. CCS leases the space in which the lab is located, owns the equipment, buys the supplies its uses (and not under

hospital purchasing contracts), and employs the nonphysician personnel working in the lab. The cardiologists who have ownership interests in the lab refer their own patients there, but nonowner cardiologists who have privileges at the adjacent hospital are permitted to use the lab, and actually do so. CCS does not compensate in any way nonowner physicians who use the lab.

The hospital conducts many open heart surgeries and otherwise has an active cardiology service. The medical office building is connected to the hospital by an overhead, enclosed walkway that goes over a city street. The medical office building is owned by the hospital and the hospital leases the space to the CCS. The medical office building is within 250 yards of the hospital and thus, is on the hospital's campus under CMS's definition. The hospital's cardiology services are located in various locations in the hospital. EKGs for nonemergent outpatients are not performed frequently, but when they are performed, they are done in a small examination room in the hospital's basement. Stress tests, including thallium stress tests are performed in a dedicated room on the hospital's third floor close to the inpatient cardiology unit, and on the opposite side of the hospital from where the medical office building walkway connects on the hospital's second floor. Finally, the hospital conducts cardiac rehabilitation services in an ambulatory care center located one block away from the hospital's main building but within 250 yards of that main building.

Many of the cardiac catheterizations are diagnostic only, but approximately 30 percent also include an interventional procedure such as implanting a stent.

The hospital does not have its own cardiac catheterization lab. All patients, including Medicare patients, receiving cardiac catheterizations at CCS's lab are registered as hospital patients. They are registered remotely on a computer located in CCS's lab. These cardiac catheterization patients do not routinely receive any services directly from the hospital as part of the same encounter during which the catheterization is performed. The CCS lab, however, is well integrated with other hospital services. For example, if a patient needs additional services indicated during the catheterization, those services are often furnished at the hospital. If patients need an extended recovery from a catheterization or complications arising from the catheterization need to be treated, the patients are almost always transferred to the hospital. Likewise if a patient presents to the hospital's emergency department and a cardiac catheterization is indicated, that patient is referred to CCS's lab. (CCS will open the lab and call in a physician and staff outside of normal hours of operation.)