

IMAGING JOINT VENTURES REGULATORY ISSUES

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The following presents an overview of certain antitrust, regulatory, and tax issues that should be considered in the planning process for a hospital-physician joint venture, and in some instances, are specific to imaging joint ventures.

I. ANTITRUST

A. *Overview*

Both the formation of a joint venture and its operation could raise antitrust issues. The purpose of the antitrust laws is to protect competition. Joint ventures are judged under the antitrust laws by considering whether the likely effect of the transaction, in light of all the circumstances, may be to lessen competition. A much stricter standard applies to agreements between competitors that fall short of a legitimate joint venture. Such agreements may be unlawful without regard to whether or not they actually lessen competition and regardless of whether they are ever implemented. For example, when a joint venture is a "sham" that does not involve true economic or clinical integration or the sharing of risk, agreements to fix prices or divide the market would be *per se* illegal.

The penalties for entering into agreements forbidden by the antitrust laws are severe (e.g., treble damages, attorneys' fees). The federal government, state governments, well as private parties have the authority to enforce these laws. Government antitrust enforcement actions may be either civil or criminal.

B. *General Rules*

From an antitrust perspective, the joint venture discussions between the proposed joint venture participants should be guided by three general rules and it is useful to educate clients on these principles, particularly when the joint venture involves the collaboration of competitors:

1. **Don't Jump the Gun**

The principal concern in joint venture discussions is to avoid any agreements or understandings, in advance of the formal agreement to form the venture, that reduce competition. It is important to understand, throughout the discussions, that the parties remain competitors and must continue to observe the antitrust laws.

2. **Don't Share Sensitive Data**

Government agencies are concerned that joint venture negotiations not be used as a pretext for the unlawful exchange of competitively sensitive information with a competitor. This

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risk is lessened when the negotiations are entered into in good faith, the information exchanged is limited to that truly necessary for the transaction to be evaluated, and the information is not used for anticompetitive purposes.

3. Don't Create Bad Documents

Finally, it is important during joint venture discussions to carefully monitor the *documents* that are created so as not to give a false impression that anticompetitive topics have been discussed, or that improper agreements have been reached.

C. *Practical Tips for Clients*

The following guidelines amplify the general rules noted above and should assist in reducing the parties' antitrust risks in pre-joint venture discussions:

- Each party must continue to make decisions concerning its operations separately during the joint venture discussions.
- No agreement or understanding (whether express or implied) should be reached during the discussions to refrain from competing.
- All agreements should be reviewed by counsel.
- Information that is exchanged should be (1) limited to information pertinent to evaluating the proposed transaction, (2) reviewed by a limited number of individuals with a "need to know," (3) used only to evaluate and plan the joint venture, and (4) returned if the venture is not completed.
- Competitively sensitive terms (including rates) of contracts with payers should not be shared. Revenue information should be aggregated to the extent practicable. Average reimbursement by payer type (HMOs, PPOs, etc.) may be exchanged as long as actual contract rates with individual payers cannot be determined from this information.
- In general there is less antitrust risk when historical information is exchanged and more risk when information concerning future conduct is exchanged.
- Information as to future plans on competitively sensitive matters should not be shared. This means, for example, that the parties should not discuss with each other what services they plan to add or drop, which payers they will or will not do business with, or the terms they plan to offer to payers.
- Participants should be aware that every document created by the parties or consultants (including notes, e-mail, computer hard drives, diary or calendar entries, correspondence, and the like) may be read by the government. Clients should take care not to use language that could be misconstrued by a third party.

- If the joint venture is not completed, a client must avoid taking any action that could suggest to the enforcement agencies that the parties entered into an informal understanding not to compete.

II. FRAUD AND ABUSE

A. *The Stark Law* (Social Security Act §1877; 42 U.S.C. §1395nn)

The federal physician self referral or (“Stark”) law prohibits a physician from referring Medicare patients for designated health services² to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. The breadth of the Stark prohibition and the complexity of its exceptions make it a factor in almost all financial relationships involving physicians and other providers. A joint venture, almost by definition, will involve a direct or indirect ownership interest on the part of the participating physicians, thereby triggering the need for Stark analysis.

The Stark law has effectively eliminated certain imaging joint ventures. Through careful planning, however, there remain a number of joint venture structures for imaging services that still can pass muster. Set forth below are some joint venture options that, if properly structured, remain viable.

1. **Equipment, Real Estate, or Management Joint Ventures**

Joint ownership of medical equipment or a medical office building may be permissible if the equipment company or real estate venture is not a provider. Similarly, a hospital and physicians or groups may jointly own and operate a management company.

2. **Joint Ventures for Ownership in an Independent Diagnostic Testing Facility**

Depending on the nature of the participants, they could jointly own an IDTF, which would become the imaging provider. A key to this arrangement is that the owners of the IDTF cannot be referral sources; therefore, this model works with hospitals, radiologists, proprietary companies or other non-referring physicians or entities as owners.

3. **Joint Ventures That Carve Out Medicare and Medicaid Patients**

Stark applies directly to Medicare patients and indirectly to Medicaid patients. If these patients are not referred to the joint venture, Stark could be avoided. The viability of this option, however, is limited when a 501(c)(3) charitable organization is involved in the venture. It is also limited depending on the particular state of location. For example, California’s “baby Stark” law (Business & Professions Code sections 650.01 and 650.02) applies to all payors.

² “Designated health services” are defined in the Stark law as (a) clinical laboratory services; (b) physical therapy services; (c) occupational therapy services; (d) radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; (e) radiation therapy services and supplies; (f) parenteral and enteral nutrients, equipment, and supplies; (g) prosthetics, orthotics, and prosthetic devices and supplies; (h) home health services; (i) outpatient prescription drugs; and (j) inpatient and outpatient hospital services. Regulations adopted January 4, 2001 and generally effective January 4, 2002 clarify the definitions of physical therapy and radiology services by tying them to specifically identified CPT codes.

4. Exceptions

In order to comply with the Stark law, a potentially prohibited arrangement must fit under the criteria for an exception. Exceptions that are most frequently used in the context of imaging joint ventures are exceptions for lease of space, lease of equipment, personal services arrangements, and the indirect compensation relationship exception. In addition, the definitions under Stark play an instrumental role in determining whether a proposed venture is permissible. Some care should be taken to ensure that the “entity” is properly identified and the source of the referral is identified as well. Under the Stark law definitions, there are occasions when an arrangement does not constitute a prohibited relationship because the referrals from the referring physician are exempt (e.g., radiologists under certain circumstances), the recipient of the referral is not an “entity” under Stark (e.g., a provider that purchases a test from a supplier), or the referral is exempt under other circumstances because it falls outside the definition of a prohibited relationship. (Note- do not try to understand the logic behind these definitional exceptions or attempt to identify some pattern or common thread. Like most of Stark, they defy logic and they simply exist. Part III of this series (not yet scheduled) will focus on coping and acceptance, all detailed in our upcoming book, *Zen and the Art of Stark Law Compliance*.)

B. *The Anti-Kickback Statute* (Social Security Act §1128B; 42 U.S.C. § 1320a-7b)

The Anti-Kickback Statute prohibits the offer, payment, solicitation or receipt of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in exchange for (i) the referral of patients covered by a federal health care program; or (ii) the leasing, purchasing, ordering or arranging for or recommending the lease, purchase or order of any item, good, facility or service covered by a federal health care program. Courts have held that an arrangement violates the Anti-Kickback Statute if one purpose of remuneration is to induce the referral of items or services to be paid by federal health care programs, even if another purpose of the payment is legitimate.

The breadth of the anti-kickback prohibition is stunning and its penalties potentially draconian (e.g., fines of up to \$25,000, imprisonment for up to five years, exclusion and civil money penalties).

1. Safe Harbors

The Office of the Inspector General (OIG) has promulgated several safe harbors to provide guidance to the industry and to protect certain arrangements from the Anti-Kickback Statute. If possible, a joint venture between should be structured either to fit within a safe harbor or to come as close as possible to doing so. Safe harbors that generally can be used for imaging joint ventures include those for a lease of equipment, a lease of space and personal services arrangements.

2. Guidelines

The following are general guidelines in reducing the risk that a joint venture might violate the Anti-Kickback statute:

- Investors should generally contribute capital or other valuable consideration to the

joint venture in proportion to their ownership interests in the venture. Profits, losses and distributions should be allocated in proportion to the investors' relative ownership interests.

- The valuation of the contributions and joint venture's ownership interests should be corroborated by independent data or expert opinion.
- If physicians invest individually in the joint venture, they generally should **not** be included or excluded based on their past patient referral patterns or propensity to refer patients.
- Care should be taken in determining what information is requested from potential physician investors to avoid the appearance that referral patterns are being taken into consideration in this process.
- The joint venture should not pay more than fair market value for any item or service.

C. *The False Claims Act* (31 U.S.C. §§ 3729 - 3732)

The False Claims Act makes it unlawful for any person to knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval. The penalty for each violation of the False Claims Act is a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains. Violations of the False Claims Act may also include criminal penalties.

In general, the False Claims Act is a concern in connection with imaging joint ventures, not only because an Anti-Kickback Statute violation could be found to also violate the False Claims Act, but violations of the Purchased Diagnostic Test Rule and/or the Purchased Interpretation Rule (see below) would most likely be found to have generated false claims prohibited by the False Claims Act.

III. PURCHASED TEST/INTERPRETATION RULE

Purchased Test Rule Medicare Carriers Manual 30.2.9 (CMS Pub. 100-04)

Purchased Interpretation Rule Medicare Carriers Manual 30.2.9.1 (CMS Pub. 100-04)

These Medicare rules set forth the guidelines with respect to billing for diagnostic tests and/or interpretations that the billing provider did not perform itself. Compliance with this rule is critical for entities involved in joint ventures to the extent that there is any question whether they actually performed the service or whether they are merely purchasers of the service. In the event the test and/or interpretation is purchased, a provider may not mark up the test/interpretation and must indicate on the invoice to Medicare that the service was purchased. This is a hot issue, particularly in connection with time-share leases where the leases are structured in a way to cause question whether the arrangement is truly a lease. What makes compliance with this rule difficult however, is the lack of enforcement or other guidance with respect to the interpretation of these rules. Notwithstanding, these issues have been identified as

areas of concern for the OIG. The rules are attached as Appendix One and Two, respectively. In 2007, CMS issued and delayed until January 1, 2009, anti-markup rules that would apply to any services provided outside the "office of the billing physician or other supplier."

IV. REASSIGNMENT RULE

Reassignment Rule (42 U.S.C. 1395u)

In addition to the purchased interpretation rule cited above, depending on the relationship among the joint venture parties and the services rendered by the billing party, issues may come up under the reassignment rule. This rule outlines exceptions to the general prohibition against a provider assigning its right to payment under the Medicare and Medicaid programs to another provider. Recent modifications to the exceptions make this rule more flexible; however, the intersection between the requirements of the reassignment rule, the in-office ancillary exception to Stark, and the purchased test/purchased interpretation rules is very unclear since these rules do not appear to reconcile with each other. While some of us at DWT have tried to obtain clarity from Region IX, it is apparent from the nonsensical responses from Region IX and the obvious confusion and disagreement by lawyers who frequently practice in this area on the AHLA list-serve that arrangements appearing to fall under reassignment, purchased test/interpretation and/or the in-office ancillary exception are thorny at best. Proceed cautiously! The latest version of the reassignment rule is attached as Appendix Three.

V. TAX ISSUES

A. Overview

1. Loss of Exempt Status

The primary tax concern with respect to joint ventures between tax-exempt and taxable organizations is the risk of private inurement or excess private benefit, which could jeopardize the exempt participant's exempt status. Private inurement is avoided if "no part of [the exempt organization's] net earnings...inures to the benefit of any private shareholder or individual." Excess private benefit should not arise if the exempt organization does not confer more than "incidental" benefits on private parties. Such benefits must be both quantitatively and qualitatively incidental.

2. Unrelated Business Income

Apart from concerns regarding exempt status, joint ventures raise the potential for unrelated business income ("UBI"). An exempt organization that carries on a trade or business is subject to tax on any net income it receives from activities that are not "substantially related" to the exempt organization's charitable purposes. Beyond the potential tax liability, the conduct of any unrelated trade or business that involves a tax-exempt bond-financed facility or equipment raises concerns regarding "private use" under the bond financing rules.

B. Joint Venture Factors

To avoid private inurement and excess private benefit in the joint venture context, three issues should be carefully examined: (1) control; (2) evidence of a charitable purpose and operations; and (3) proper valuation of contributed assets.

1. Control

The IRS has indicated that in for-profit/nonprofit joint ventures majority control by the exempt organization is “one of the most important favorable factors in establishing that profit motives do not subvert the charitable mission.” A favorable joint venture governance structure would allow the exempt organization to appoint a majority of the joint venture’s board members, and ideally requires either a majority of the exempt organization’s board members for a quorum, or supermajority voting for certain actions.

If the exempt organization lacks formal voting control of the joint venture, then it must have another mechanism to ensure the joint venture will operate to further the exempt organization’s charitable purposes. Reserved powers or similar safeguards can be used to achieve this goal.

2. Charitable Purpose and Operations

The joint venture documents (including any management agreement) should include a clear statement that indicates that the joint venture will be operated in a manner that is consistent with the exempt organization’s charitable purposes. The structure of the venture should also support the achievement of the stated charitable purpose.

Regardless of the formal documents or structure, however, the IRS is likely to examine whether joint venture operations *in fact* further exempt purposes. Simply stating in the joint venture documents that exempt purposes should prevail will not be sufficient to demonstrate that the enterprise promotes the organization's charitable mission. Actual evidence of joint venture operations in furtherance of exempt purposes is required.

3. Proper Valuation of Assets Contributed

Another area of regulatory concern is whether assets contributed by the exempt organization are properly valued. The IRS has stated that in order to ensure that a for-profit partner does not receive undue private benefit from a joint venture arrangement, “a proper valuation of interests is essential in determining that ownership interests of the tax-exempt organization in the joint venture are proportionate to and equal in value to what it has contributed to the joint venture.”

VI. STATE LAW

In structuring any arrangement, one should ensure that the proposed arrangement complies with applicable state law. In particular, the following areas of state law may dictate the form of the arrangement, reimbursement structure/analysis, business case, and participating parties:

- State licensing issues - Will the joint venture be a provider? If so, how will it be licensed? A clinic? A physician office? Hospital-based service?
- Corporate practice of medicine doctrine/fee splitting - If the joint venture is a provider, what services will it be able to provide? Is it limited to technical services only? Who can be an owner? Who will supervise the clinical services and under what fee arrangement?
- Certificate of Need – Is this required?
- State anti-kickback and physician self-referral prohibitions – These laws are usually not identical to the federal laws, and frequently have different requirements. Note in particular California’s “baby Stark” law, which is materially different from Stark and applies to all payors.

Appendix One

§30.2.9 - Payment to Physician or Other Supplier for Purchased Diagnostic Tests - Claims Submitted to Carriers

(Rev. 464, Issued: 02-04-05, Effective: 04-01-05, Implementation: 04-04-05)

A physician or a medical group may submit the claim and (if assignment is accepted) receive the Part B payment, for the technical component of diagnostic tests which the physician or group purchases from an independent physician, medical group, or other supplier. (This claim and payment procedure does not extend to clinical diagnostic laboratory tests.) The purchasing physician or group may be the same physician or group as ordered the tests or may be a different physician or group. An example of the latter situation is when the attending physician orders radiology tests from a radiologist and the radiologist purchases the tests from an imaging center. The purchasing physician or group may not markup the charge for a test from the purchase price and must accept the lowest of the fee schedule amount if the supplier had billed directly; the physician's actual charge; or the supplier's net charge to the purchasing physician or group, as full payment for the test even if assignment is not accepted. (See section 10.1.1.2 for additional information on purchased diagnostic tests.)

In order to purchase a diagnostic test, the purchaser must perform the interpretation. The physician or other supplier that furnished the technical component must be enrolled in the Medicare program. No formal reassignment is necessary.

Effective for claims received on or after April 1, 2004:

- In order to have appropriate service facility location ZIP code and the purchase price of each test on the claim, when billing for purchased tests on the Form CMS-1500 paper claim form each test must be submitted on a separate claim form. Treat paper claims submitted with more than one purchased test as unprocessable per §80.3.2.
- More than one purchased test may be billed on the ANSI X12N 837 electronic format. When more than one test is billed, the total purchased service amount must be submitted for each service. Treat claims received with multiple purchased tests without line level total purchased service amount information as unprocessable per §80.3.2.
- Treat paper claims submitted for purchased services with both the interpretation and the purchased test on one claim as unprocessable per §80.3.2 unless the services are submitted with the same date of service and same place of service codes. When a claim is received that includes both services, and the date of service and place of service codes match, assume that the one address in Item 32 applies to both services. *Effective for claims with dates of service on or after April 1, 2005, each component of the test must be submitted on a separate claim form. Treat paper claims with dates of service after March 31, 2005 submitted with more than one purchased test as unprocessable per §80.3.2.*
- ANSI X12N 837 electronic claims submitted for purchased services with both the

interpretation and purchased test on the same claim must be accepted. Assume that the claim level service facility location information applies to both services if line level information is not provided.

In order to price claims correctly and apply purchase price limitations, global billing is not acceptable for claims received on the Form CMS-1500 or on the ANSI X12N 837 electronic format. Each component must be billed as a separate line item (or on a separate claim per the limitations described above). Treat the claim as unprocessable per §80.3.2 when a global billing is received and there is information on the claim that indicates the test was purchased.

Effective for claims with dates of service on or after *January 25, 2005*, carriers must accept and process claims for purchased diagnostic tests when billed by suppliers (including laboratories, physicians, and independent diagnostic testing facilities [IDTFs]) enrolled in the carrier's jurisdiction, regardless of the location where the service was furnished. *Effective April 1, 2005, carriers must price purchased diagnostic test claims based on the ZIP code of the location where the service was rendered when billed by a laboratory or an IDTF, using a CMS-supplied abstract file of the Medicare MPFS containing the HCPCS codes that are payable under the MPFS as either a purchased test or interpretation for the calendar year. (See IOM Publication 100-04, chapter 23, §30.6, and Addendum for record layouts and instructions for downloading the Abstract File for Purchased Diagnostic Tests/Interpretations.) Until further notice, carriers must pay the local rate for purchased diagnostic test claims when submitted by a physician.*

NOTE: As with all services payable under the MPFS, the ZIP code is used to determine the appropriate payment locality and corresponding fee for the purchased test/interpretation. When a ZIP code crosses locality lines, CMS uses the dominant locality to determine the corresponding fee.

Appendix Two

§30.2.9.1 - Payment to Supplier of Diagnostic Tests for Purchased Interpretations

(Rev. 464, Issued: 02-04-05, Effective: 04-01-05, Implementation: 04-04-05)

A person or supplier that provides diagnostic tests may submit the claim, and (if assignment is accepted) receive the Part B payment, for diagnostic test interpretations which that person or entity purchases from an independent physician or medical group if:

- The tests are initiated by a physician or medical group which is independent of the person or entity providing the tests and of the physician or medical group providing the interpretations;
- The physician or medical group providing the interpretations does not see the patient; and
- The purchaser (or employee, partner, or owner of the purchaser) performs the technical component of the test. The interpreting physician must be enrolled in the Medicare program. No formal reassignment is necessary.

The purchaser must keep on file the name, the provider identification number and address of the interpreting physician. The rules permitting claims by a facility or clinic for services of an independent contractor physician on the physical premises of the facility or clinic are set forth in §§30.2.7 and 30.2.8.3.

NOTE: This change does not negate the requirement that when an entity either purchases an interpretation or a test, they themselves must perform the other component in order to be paid for the purchased component.

Effective for claims with dates of service on or after *January 25, 2005*, carriers must accept and process claims for purchased diagnostic interpretations billed by suppliers (including laboratories, physicians, and independent diagnostic testing facilities [IDTFs]) enrolled in the carrier's jurisdiction, for services furnished anywhere in the United States. *Effective April 1, 2005, carriers must price claims for purchased interpretations based on the ZIP code of the location where the service was rendered when submitted by a laboratory or IDTF, using a CMS-supplied abstract file of the MPFS containing the HCPCS codes that are payable under the MPFS as either a purchased test or interpretation for the calendar year. (See IOM Publication 100-04, chapter 23, §30.6, and Addendum for record layouts and instructions for downloading the Abstract File for Purchased Diagnostic Tests/Interpretations.) Until further notice, carriers must pay the local rate for purchased interpretation claims when submitted by a physician.*

NOTE: As with all services payable under the MPFS, the ZIP code is used to determine the appropriate payment locality and corresponding fee for the purchased test/interpretation. When a ZIP code crosses county lines, CMS uses the dominant locality to determine the corresponding fee.

Appendix Three

Reassignment Rule (42 U.S.C. § 1395u)

[. . .]

- (b) (6) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that
- (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his employment to turn over his fee for such service to his employer, or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate,
 - (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part,
 - (B) in the case of services described in clause (i) of section 1861(s)(2)(K), payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1861(aa)(2)) for a continuous period beginning prior to the date of the enactment of the Balanced Budget Act of 1997 and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1861(aa)(2), payment may be made directly to the physician assistant,
 - (C) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-

time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days; and (iv) the claim form submitted to the carrier for such services includes the second physician's unique identifier (provided under the system established under subsection (c)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or entity as described in subparagraph (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment,

[. . .]

- (G) in the case of services in a hospital or clinic to which section 1880(e) applies, payment shall be made to such hospital or clinic.