

DISCOVERY

MARKET SOLUTIONS FOR THE HEALTH CARE INDUSTRY

The Real Deals in Health Care

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Over the last few months, several regulatory developments have taken place that will shape the nature of equity joint ventures between and among physicians and hospitals for the foreseeable future. With the recent specialty hospital moratorium passed as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the issuance of final regulations under the federal physician self-referral statute known as the “Stark Law” and the issuance of additional joint venture

guidance by the Internal Revenue Service for for-profit/nonprofit joint ventures, many providers may wonder what types of deals they should pursue in this environment. While the fate of specialty hospitals as future equity vehicles remains unclear, the regulatory landscape is really quite stable, and hospital and physician health care providers alike may proceed with confidence on the *Real Deals* that have clearly become accepted parts of the health care provider landscape. This article discusses the *Real Deals* that providers are successfully deploying in the marketplace, and will also review the recent relevant regulatory and tax guidance for the *Real Deals*. While

physicians and hospitals may choose not to partner in new joint ventures, this article focuses on opportunities for hospitals and physicians to work together as partners and align their interests in delivering care through new ventures.

The *Real Deals* fall into two broad categories: equity joint ventures that operate as health care providers; and equity joint ventures that furnish facilities, equipment or services to health care providers. For example, a joint venture ambulatory surgery center between a hospital and allied physicians is the most familiar health care provider joint venture; while a service company organized to finance and furnish

capital-intensive equipment and services for an imaging center is an example of a joint venture that provides equipment and services to the health care provider.

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Hospitals and physicians may find joint ventures particularly useful where new health care markets are emerging.

PROVIDER DEALS


As a general matter, physicians and hospitals will only partner in the development and operation of a health care provider where the Stark Law permits the physicians to maintain an ownership interest in the health care provider. The Stark Law prohibits a physician from referring patients for certain “designated health services” that are reimbursable by Medicare to any entity with which the physician has a financial relationship, unless an exception to the statute applies. Although there are very few exceptions to the Stark Law that permit physicians and hospitals to jointly own and operate a health care provider, physicians and hospitals may share ownership in a general acute care hospital, or they may share ownership in an ambulatory surgery center (ASC) because a physician’s ownership of each of those providers is excepted from the prohibitions under the Stark Law. In particular, the Stark Law provides that physicians may maintain an ownership interest in a whole hospital (but not a subdivision, part or department of a hospital) if the physician owners are authorized to perform services at the hospital, and this opportunity remains available for ownership in general acute care hospitals despite the current

federal moratorium on so-called specialty hospitals.¹ Long term acute care hospitals (“LTACs”) also qualify as full-service acute care hospitals and physician ownership is not restricted by the specialty hospital moratorium.

In the case of the ASC, the Stark Law does not preclude a physician from referring a patient to an ASC owned by the physician for services paid by Medicare on a composite basis, including certain Stark designated health services that are directly and integrally related to the primary procedures performed at the ASC.

The federal anti-kickback statute also provides very clear guidance with respect to ASCs and provides protection for physician and hospital ownership in an ASC. The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program, including, but not limited to Medicare and Medicaid. Although joint ventures by physicians and hospitals are susceptible to fraud and abuse, the Office of the Inspector General (the “OIG”), which is charged with the responsibility of overseeing compliance with the anti-kickback statute, recognized that precluding joint

¹ This article does not address the development of specialty hospitals or the current moratorium which provides that for the 18-month period beginning on December 8, 2003, a physician may not make referrals to a specialty hospital in which he or she has an ownership interest. The hospital moratorium is contained in Section 507 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) and defines “specialty hospital” as a hospital that is primarily or exclusively engaged in the care and treatment of one of the following: patients with a cardiac condition; patients with an orthopedic condition; patients receiving a surgical procedure; or any other specialized category of services that the Secretary for the Centers for Medicare and Medicaid Services designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital. A “specialty hospital” does not include any hospital (1) determined by the Secretary to be in operation before or under development as of November 18, 2003; (2) for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date; (3) for which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date; (4) for which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and (5) that meets such other requirements as the Secretary may specify.





ownership of ASCs could place hospitals at a competitive disadvantage by forcing them to compete with ASCs owned by physicians, who principally control referrals. Thus, the OIG promulgated a safe harbor for ASCs jointly owned by physicians and hospitals that meet certain conditions. Among other things, the safe harbor is carefully circumscribed to apply only to physicians who are unlikely to use the investment as a vehicle for profiting from their referrals to other physicians using the ASC. Accordingly, safe harbor protection is limited to physician-investors who actually use the ASC on a regular basis as part of their medical practices or who practice the same specialty as other physician-investors and are therefore unlikely to refer substantial business to “competing” physician-investors when they can earn the fees themselves.

While the ASC anti-kickback safe harbor does not extend to a physician’s ownership of a hospital, the ASC anti-kickback safe harbor and advisory opinions issued by the Office of the Inspector General provide very useful guidance and can be used as a template for structuring physician and hospital ownership of a full-service acute care hospital. For example, Advisory Opinion 2003-2 identifies safeguards the hospital can put in place to assure the regulators that the hospital’s ability to direct or influence the referrals of its employees, independent contractors

and medical staff members to the jointly owned hospital is appropriately constrained and to assure the regulators that the physician investors actually use the jointly owned hospital as an extension of their practice.

Hospitals and physicians may find hospital joint ventures and ASC joint ventures particularly useful where new health care markets are emerging, and the hospitals and the physicians desire to develop those new markets in a collaborative fashion. For example, if a group of physicians and their current hospital leadership have identified a growing suburban population that demands health care service and better access than can be provided from the current available infrastructure, the parties may come together to develop a common business plan in which the capital resources and the professional physician resources will be deployed in tandem, and will dramatically enhance the likelihood of success of a new hospital or ASC. This approach is particularly effective in aligning the interests of the physicians and the hospitals where a new market is to be served, and the joint venture does not constitute a conversion or “carve-up” of existing health care services that are provided by existing physician and hospital players. Unlike





the uncertainty surrounding specialty hospitals, ASCs may be tailored to focus on single specialty surgeries. Common examples include orthopedic ASCs, endoscopy surgery centers and cosmetic surgery centers.

In addition to joint ventures of hospitals and ASCs, physicians and hospitals may consider creating a joint venture to jointly own and operate an independent diagnostic and treatment facilities (“IDTFs”). Under certain circumstances, a particular outpatient therapeutic service which would be subject to the Stark Law’s prohibitions if delivered as an outpatient hospital service may be delivered through an IDTF not subject to Stark Law’s prohibitions. For example, a free-standing *diagnostic only* cardiac catheterization lab is not considered a Stark designated health service and may be operated as an IDTF and jointly owned by a hospital and physicians. The IDTF bills in accordance with the physician fee schedule, and may only perform cardiac catheterizations that are permitted to be performed in an outpatient setting. Similarly, an IDTF may be used to operate a PET scanner or provide nuclear imaging, because

these imaging modalities are not Stark designated health services. These joint ventures of IDTFs, however, will not qualify for anti-kickback safe harbor treatment unless they fall under the safe harbor for small investment interests.

The investment interest safe harbor for small entities excludes from the definition of “remuneration” any payment that is a return on an investment interest made to an active or passive investor when eight standards are met. Among other things, the eight standards require that no more than 40 percent of the investment interests of the entity may be held 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 except if the entity is located in a medically underserved area, in which case 50 percent of the investment interest may be held by investors who are in a position to make or influence referrals. In addition, no more than 40 percent of the gross revenue of the entity may come from referrals or

business otherwise generated from investors unless the entity is located in a medically underserved area in which case there is no limit the amount of revenue that can be generated by the parties in a position to refer.

The failure to qualify for a safe harbor does not automatically indicate that an arrangement violates the anti-kickback statute.

Rather, the arrangement is subject to examination on a case-by-case basis to determine whether the purpose was to improperly induce referrals. Therefore, joint ventures not falling within the investment interest safe harbor should consider using certain safeguards previously approved by the OIG in various Advisory Opinions addressing joint ventures involving ambulatory surgical centers. Although these Advisory Opinions are specific to the facts presented in the Advisory Opinions, they can be useful guidance for future joint ventures. For example, a joint venture should (1) disburse joint venture profits based solely on each investor's percentage of capital ownership rather than on the value or volume of referrals; (2) prohibit the investor-hospital from requiring or encouraging hospital physicians to refer patients to the joint venture; (3) prohibit the tracking of any referrals by physicians associated with the hospital to the joint venture; and (4) prohibit tying hospital-employed physician compensation to any volume or value of referrals to the joint venture.


Moreover, any ancillary agreements between joint venture investors should be of at least one year in duration and any renewal should not be subject to the volume or value of referrals that occur between the parties.

NON-PROVIDER DEALS

As noted at the outset, hospitals and physicians may pursue numerous avenues as equity partners in ventures that develop and furnish facilities, equipment or supplies to the ultimate health care provider. For example, even though the Stark Law prohibits an equity joint venture between physicians (other than radiologists, pathologists and radiation oncologists, all of whom are deemed not to be in a position to refer when acting pursuant to a consultation request by another physician) and a hospital for an imaging center, physicians may partner with a hospital to own an imaging services company that could develop the facility and finance the capital equipment and provide the technical staff to operate it on a turnkey basis for either the hospital as the ultimate provider, or for the physician group as the ultimate provider.

If the parties formed a joint venture imaging services company to own facilities, equipment and supplies used in imaging, the venture could lease the

The failure to qualify for a safe harbor does not automatically indicate that an arrangement violates the anti-kickback statute.



facility and furnish services to both the physician practice and the hospital, if structured properly. In either case, the imaging services company would need to enter into lease and services agreements with the ultimate provider on a fair market value fee basis, with agreements that would comply with the personal services or facility or equipment rental exceptions of the Stark Law and ideally, comply with the anti-kickback safe harbors that cover the same arrangements, each of which, among other things, require that the agreement be in writing for a term of at least one year, specify the intervals of use, and provide for fair market value compensation which is set in advance and in the aggregate. In addition, because the joint venture is not itself a health care provider billing for services reimbursable by Medicare, the Stark Law does not prohibit a physician from having an ownership interest in the imaging services company. However, the Stark Law would prohibit the physician from entering into a lease of the facility and services from the imaging services company and billing for the services unless the physician's services met the in-office ancillary exception of the Stark Law.

In addition, where a physician practice bills for a diagnostic test performed by an outside supplier, the purchasing physician group may not mark up the charge for a test from the purchase price paid to the supplier 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. Medicare and certain third party payers have raised concerns about lease arrangements that create an appearance that the physician has performed the test or supervised the technicians provided by the supplier who performed the test but do not appropriately shift the risk of providing the service to the physician or group. Thus, the lease between the imaging services company and the physician should shift sufficient risk to the leasing physician to ensure that the leasing physician is actually providing the services.

Because any equity venture that furnishes facilities, equipment or supplies to a health care provider may appropriately qualify for the available Stark exception and anti-kickback safe harbors, there is very little to limit the types of facilities, services or equipment these ventures might provide, with one caveat: the compensation to be paid to the services company must be consistent with fair market value in order to comply with the Stark Law, the federal anti-kickback statute and tax exemption requirements of the hospital which is likely to be tax exempt. In addition, the parties may choose to eliminate any anti-kickback risk by developing rental and service agreements that clearly comport with the requirements of the anti-kickback safe harbors. These safe harbors generally track the requirements of the Stark exceptions; however, the anti-kickback safe harbors require the compensation to be set in advance and in the aggregate for a minimum term of one year.



In some cases, the parties may not be able to set the compensation in the aggregate with any certainty and may desire to lease the facility or purchase the services on a per scan or half-day basis. Although an arrangement that does not fit within a safe harbor is not necessarily unlawful, it is not free from regulatory scrutiny, and the arrangement and the intent of the parties would be analyzed on a case-by-case basis. The Center for Medicare and Medicaid Services has noted its disfavor for arrangements that include per use compensation, noting in its comments to the lease safe harbor that

“arrangements that use ‘per use’ or similar ‘per click’ fees are often abusive and should be reviewed on a case-by-case basis. Further as noted above, it is important to shift sufficient risk to the leasing physician to ensure that the leasing physician is providing the services, not simply purchasing the diagnostic test to avoid the appearance that the physician is attempting to circumvent the prohibition on marking up purchased diagnostic services. Thus, the longer the period of time and the more risk being borne by the provider, the less regulatory risk is posed by the joint venture.


Provider Joint Ventures

- ASCs
- Endoscopy Centers
- JV Whole Hospitals
- JV LTACs
- JV IDTFs for certain non-designated health services (non DHS services)

Non-Provider Joint Ventures

- Ambulatory Facility Building
- Facility Partnerships
- Radiology Equipment Lease and Service Arrangements
- Cath Lab Outsourcing
- Arrangements involving Lease of Cardiac Cath Lab equipment and provision of Cath Lab staff services
- JV of PET Scanner






The organizing documents of the proposed joint venture should acknowledge the hospital's exempt status and establish the priority of the hospital's charitable purposes over the profit motives of the joint venture.

TAX-EXEMPTION PRINCIPLES OF JOINT VENTURING

Both types of *Real Deals* described above involve joint ventures between physicians and hospitals which are often tax exempt. When a tax exempt hospital engages in a joint venture activity with for-profit co-venturers there are two important tax concerns: (1) the impact of the joint venture upon the exempt organization's continuing qualification for tax-exempt status; and (2) the tax treatment of the exempt organization's income and expenses arising from its participation in the joint venture. As a general rule, an exempt organization may participate in a joint venture with a for-profit organization and maintain its exempt status, provided that all contributions to the joint venture by any party are fairly valued and that allocation of equity (ownership) accurately reflects these contributions and that the joint venture activity is relatively insubstantial relative to the exempt organization's total activities. Income to the exempt organization from such a joint venture will either be considered related exempt income or unrelated business taxable income depending on the nature of the joint venture activities and the exempt organization's degree of control over the joint venture.

Prominent cases and Internal Revenue Service rulings that analyze joint ventures between exempt hospitals and for-profit co-venturers focus on the necessity of the exempt hospital maintaining sufficient control over the joint venture. However, each of the joint ventures at issue in the cited cases and rulings were so-called "whole hospital" joint ventures in which essentially all of the exempt hospital partner's charitable activities are provided by and through the joint venture entity. Earlier this month, the Internal Revenue Service issued a new revenue ruling 2004-5 analyzing an ancillary joint venture between an exempt university and a for-profit co-venturer. Notably, this revenue ruling indicates that for an ancillary joint venture that is an insubstantial part of an exempt organization's total activities, the issue of the exempt organization's control over the joint venture is not central (as it is in the "whole hospital" context). Instead, as set forth below, control by the exempt organization is an effective means by which to assure that income from the joint venture to the exempt partner will not be considered unrelated business taxable income.



In order to assure that the activities of the proposed joint venture are viewed as related to the hospital's exempt purpose and are not treated as unrelated taxable activities, the joint venture should be structured and operated so that the joint venture's profit motivation is subordinate to the delivery of these services in a charitable manner. The primacy of the exempt purpose should be set forth in the joint venture's organizing documents (articles of organization, member agreements, etc.). To that end, the organizing documents of the proposed joint venture should acknowledge the hospital's exempt status and establish the priority of the hospital's charitable purposes over the profit motives of the joint venture. Further, the organizing documents should include at least (a) and (b) from the following list, and (c), (d), and (e), as appropriate, in order to establish that the joint venture satisfies the so-called "community benefit standard":


- (a) the joint venture will treat Medicare and Medicaid patients in the same relative proportion as are treated by Tax exempt hospital;
- (b) the joint venture will establish and implement a written charity care policy that is comparable to Tax exempt hospital's policy for similar services;
- (c) as appropriate, the joint venture will maintain an open medical staff;

- (d) as appropriate, the joint venture will provide public health programs of educational benefit to the community; and
- (e) the joint venture will promote the health, wellness and welfare of the community by providing quality health care at a reasonable cost.

The best way for the exempt organization to assure that the joint venture is actually operated in compliance with the exempt organization's purpose and the "community benefit standard" terms set forth above, is for the exempt organization to have certain controlling powers over the operations of the joint venture. The various "whole hospital" joint venture cases and revenue rulings provide useful guidance regarding the control features that should be built into the organizing documents of the joint venture to assure compliance with the exempt organization's exempt purpose.

If the exempt organization has a majority ownership in the joint venture and control of the venture's governing board, it should have the ability to assure that the joint venture is operated in furtherance of the exempt organization's exempt purpose. In the absence of majority ownership in the venture and control of the venture's governing board, the exempt partner should have the power to cause the venture to operate in compliance with its charitable purpose (not just the power to veto certain activities that are inconsistent with its charitable






purpose). Thus, where an exempt organization does not have control through ownership and governing board dominance, it should obtain effective control through “reserved powers” (or other means) over decisions that could affect whether the venture is operated in furtherance of the exempt organization’s purposes. Through such “reserved powers,” the exempt organization could obtain the following powers that should enable it to assure that the joint venture will operate in furtherance of exempt purposes:

- (a) authority to cause the venture to operate consistent with the “community benefit standards” set forth in the organizational documents (described above);
- (b) power to appoint the chair of the Board (affording the exempt organization greater influence over the Board’s agenda); and
- (c) power to unilaterally hire and remove the joint venture’s CEO (affording the exempt organization indirect influence over the day-to-day operations of the joint venture).

If the joint venture may contract with an individual or other for-profit entity (including either of the for-profit partners or their principles or employees) to manage the joint venture, and if the hospital does not have effective control over the selection and terms through ownership or governing board dominance, the following protections should be put in place to assure that the hospital retains essential controls over the for-profit manager’s compliance with exempt purposes:

- (a) term of the management agreement should be reasonable and should provide tax exempt hospital with the sole discretion on whether to renew without substantial penalty for early termination;
- (b) tax exempt hospital should retain the right to unilaterally terminate the management agreement for manager’s failure to operate the joint venture in accordance with the “community benefit standard” terms in the organizing documents;
- (c) terms and conditions of the management agreement should be reasonable and comparable to similar arrangements in the marketplace;
- (d) if the management fee is based on a percentage of net revenue, the management fee computation should have protections to reduce the incentive for the for-profit manager to incentivize profits to the detriment of charitable goals (one



approach would be to pay the manager a fixed fee with incentives based on other targets such as controlling expenses or achieving certain quality scores);

- (e) tax exempt hospital should require periodic reporting from the manager (with audit and inspection rights) so that patterns of inappropriate decisions can be remedied and terminated and other rights enforced if the pattern reflects a breach of the “community benefit standard” terms in the organizing documents.

SUMMARY


Although the regulatory landscape is filled with twists and turns, properly navigated, it is rich with opportunity for physicians and hospitals to align their interests in delivering care through new ventures.

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