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AMBULATORY SURGERY CENTERS BUSINESS AND LEGAL UPDATE

Provider-Based Joint Ventures—Fair Game or Gaming the System?

By: Scott Becker, Krist Werling and Amber McGraw Walsh

Hospitals and physicians are increasingly examining various types of "provider-based" joint ventures. Under this type of venture, a new entity that is partially owned by both the hospital and physicians is formed. This new entity acts as the actual provider of surgical services. It owns and operates the equipment, employs most of the staff, leases space from the hospital and holds the other assets related to the provision of surgical services. This entity contracts with the hospital to provide surgical services to the hospital's patients. The joint venture entity is operated as a technical matter, under the hospital's license and staff bylaws. The hospital bills for the services that are provided under the hospital's license and billing number as hospital services. In exchange, the hospital pays the joint venture a "fair market value" fee for providing the surgical services. Essentially, the hospital is purchasing the surgical services from the venture and billing the services under its own license.

This provider-based model has gained popularity recently amongst hospitals and physician groups seeking to take advantage of the "provider-based" and "under arrangements" rules that have evolved over the past several years. The following are several of the key risks attendant to this type of proposed model:

A. Federal Anti-Kickback Statute

The Anti-Kickback Statute[1] prohibits the knowing and willful solicitation, receipt, offer or payment of "any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in return for or to induce the referral, arrangement or recommendation of Medicare or Medicaid business." Violation of the Anti-Kickback Statute can result in both civil and criminal penalties. Federal courts have held that an arrangement violates the Anti-Kickback Statute if any one purpose of remuneration is to induce the referral of patients covered by the Medicare or Medicaid programs.

The Department of Health and Human Services has promulgated certain safe harbors which exempt a variety of financial and compensation relationships from violation of the Anti-Kickback Statute. Safe harbors exist for space and equipment rental, small investment interests and surgery center ownership, among other things. However, the provider-based joint venture structure would not precisely meet the terms of any of these safe harbors. The fact that a financial relationship does not meet the requirements of a safe harbor does not mean that such relationship is per se illegal. However, the payment of a "per click" fee in exchange for the provision of surgical services which are billed under the hospital's billing number could be interpreted to be payments which are intended to induce referrals of patients to the hospital for services. As such, there is a risk that the proposed joint venture structures could be interpreted to violate the Anti-Kickback Statute, i.e., paying an amount with the intent of inducing the referral of business.

In 2003, the Office of the Inspector General ("OIG") issued a Special Advisory Bulletin regarding contractual joint ven-

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EASC Development: Steps to Success

By: John Poisson, Executive Vice President & Strategic Partnerships Officer, Physicians Endoscopy, LLC; 215-589-9003

A variety of critical elements must be addressed as part of a comprehensive planning strategy to successfully develop an EASC. Although each EASC project is unique to its local environment, there are universal components that each owner must understand and address upfront.

The Regulatory Environment

EASCs are highly regulated, and operate pursuant to dramatically different rules than your professional practice.

At the Federal level, the primary concept to understand is the "Anti-Kickback Law", which is interpreted to cover any arrangement where one purpose is to induce or increase referrals. Simply put, a cash (or even non-cash) arrangement designed to induce a referral is illegal. You may also hear concerns regarding the "Stark Law", which indicates a physician may not make a referral to an entity for the furnishing of a designated health service if the physician or immediate family member has a financial relationship with the entity. The good news here is that EASCs are not a designated health

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tures. In the Special Advisory Bulletin the OIG commented on "questionable contractual arrangements where a health care provider in one line of business expands into a related health care business by contracting with an existing provider of a related item or service to provide the new item or service to the Owner's existing patient population, including federal health care program patients." The Bulletin discouraged such arrangements as potentially in violation of the Anti-Kickback Statute due to the risk of payments to joint venture partners being interpreted as remuneration paid in exchange for referrals.

B. The Stark Act

The Stark Act[2] restricts a physician from having a financial or compensation relationship (including an ownership interest) with any entity that provides certain "designated health services." Designated health services include inpatient and outpatient hospital services. In the proposed joint venture whereby the physician would have an ownership interest in a "provider-based" entity, the physician would arguably have an ownership interest in an entity which would provide inpatient and/or outpatient hospital services. In order to qualify for "provider-based" status, the entity would provide services that would be billed through the Hospital. The joint venture may be contracting with the Hospital to provide services "under arrangements" with the hospital. In regulations promulgated under the Stark Act, the Department of Health and Human Services stated:

> We are concerned that the provision of services "under arrangements" could be used to circumvent the prohibition [of the Stark Act] of physician ownership of parts of hospitals. We understand that some hospitals are leasing hospital space to physician groups, which the groups then use to provide services "under arrangements" that the hospital had previously provided directly. These arrangements, especially when they involve particularly lucrative lines of business, raise significant issues under [the Stark Act], as well as the anti-kickback statute.[3]

Therefore, an ownership interest in an entity such as this model and the related relationship with the hospital may be characterized as a circumvention scheme under the Stark Act. Thus, even though the Stark Act does not prohibit per click payments, it does not mean that the model is permissible.

C. 501(c)(3) Tax-Exempt Status

Many hospitals are tax-exempt entities that are obligated to serve charitable purposes. Internal Revenue Service ("IRS") regulations restrict hospitals and other tax-exempt entities from making any payments which would constitute private benefit or private inurement.[4] A tax-exempt hospital must be exclusively operated for charitable purposes and

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none of the Hospital's assets may inure to the benefit of an individual. There has been significant concern raised related to certain types of joint ventures between hospitals and physicians as to whether such ventures jeopardize the tax-exempt status of a hospital. In General Counsel Memorandum 39862, the Internal Revenue Service negatively commented on joint ventures characterized as "net revenue stream" joint ventures.[5] Such ventures are characterized by a hospital or other exempt health entity entering into a partnership or joint venture with a physician which essentially allows the physician to participate in the net revenue of a hospital and encourages referrals to a hospital. The IRS concluded that:

> A hospital entering into such a transaction jeopardizes its tax-exempt status for at least three reasons. First, the transaction causes the hospital's net earnings to inure to the benefit of private individuals. Second, the private benefit stemming from such a transaction cannot be considered incidental to the public benefits achieved. Third, such a transaction may violate federal law.

In addition to concerns relating to potential private inurement, transactions with a tax-exempt hospital that do not meet certain qualifications may be characterized by the IRS as an "excess benefit" transaction. If the IRS were to deem earnings from a joint venture with a tax-exempt hospital as "excess benefit" compensation, then such compensation could be subject to an excise tax.[6]

D. False Claims Act

Individuals or entities that knowingly file fraudulent or false claims that are payable by the Medicare program are subject to both criminal and civil liability under the False Claims Act. False Claims Act liability may be triggered when: 1) providers submit claims for medically unnecessary services; 2) providers use improper coding or billing practices ; 3) a provider submits a claim for services not provided or covered under a federal program; 4) a provider excluded from a federal program submits claims; 5) a provider violates a statute or regulation; 6) a provider falsely certifies it has complied with certain statutes or regulations; or 7) a provider submits claims for services which do not meet quality of care standards. Where a venture attempts to take advantage of a higher provider-based billing scheme and it is operating in a manner that is really akin to a freestanding facility, it could subject itself to claims of false or improper billing.

In sum, there are a variety of risks that accompany the use of a "provider-based" or "under arrangements" model for a joint venture between a hospital and a physician group. These risks include potential liability under the Anti-Kickback Statue, the Stark Act, IRS rules and regulations and the False Claims Act. Hospitals and physicians should therefore be discouraged from implementing such a model. ■

[1] 42 U.S.C. Section 1320a7-b(b).
[2] 42 U.S.C. 1395nn.
[3] 66 Fed. Reg. 942 (January 4, 2001).
[4] Treas. Reg. § 1.501(c)(3).
[5] General Counsel Memorandum 39862 (Nov. 22, 1991).

Professional Courtesy at a Surgery Center

By: Scott Becker and Amber Walsh

We recently were asked a question regarding the possible waiver of co-payments and waivers for surgeons who are on Medical Staff of and have surgery as patients at a surgery center (the "Center"). This Memorandum outlines the Stark Act exception for professional courtesy discounts and sets forth the requirements that must be met to fall within the exception. Although the Stark Act does not technically apply to the Center, we believe these are reasonable standards to follow. As you know, the Stark Act prohibits a physician from making referrals for certain designated health services ("DHS"), including inpatient and outpatient hospital services, payable by Medicare to an entity with which the physician has a financial relationship, either through ownership or compensation. However, there are numerous exceptions for various types of ownership and compensation relationships, including an exception from the restrictions of the Stark Act for the provision of free or discounted care to physicians, staff or their family members, which is commonly referred to as "professional courtesy."

Professional courtesy is defined in 42 C.F.R. § 411.353 as the provision of free or discounted health care items or services to a physician or to a physician's immediate family or office staff. Items provided as professional courtesy are exempt from the referral prohibition if they meet the following requirements:

1. The professional courtesy must be offered to either (a) all physicians on the entity's bona fide medical staff or (b) all physicians in the entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties.
2. The free or discounted health care items and services that are provided must be of a type routinely provided by the entity.
3. The professional courtesy policy must be set out in writing and approved in advance by the entity's governing body.
4. The professional courtesy may not be offered to a physician (or immediate family member) who is a federal health care program beneficiary (i.e., Medicare or Medicaid patient), unless there is a good faith showing of financial need.
5. If the professional courtesy involves any whole or partial reduction of any co-insurance obligation (i.e., co-payment or deductible), the insurer must be informed in writing of the reduction.
6. The arrangement must not violate the anti-kickback statute or any federal or state requirements governing billing or claims submission.

If a center would like to waive co-payments or deductibles for the surgeons who are on a center's Medical Staff, all six requirements must be satisfied in order for the waiver to fit within the professional courtesy exception (including prior notification to the applicable insurers in writing). While this does not make a center immune under the kickback statute, it should help improve the defensibility of the situation. ■

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service. Also at the Federal level, prior to opening, your EASC must undergo a Medicare survey. The CMS 855B form (Medicare enrollment form) must be approved before survey can proceed; it is recommended that you submit your form 2-4 months prior to completion of construction.

At the state level, an EASC must undergo a comprehensive architectural design review (your local municipality will also require this) as well as a licensure review, which is performed via an onsite survey.

Many third party payers (such as Blue Cross), have their own processes for enrollment and contracting and increasingly require the EASC to obtain accreditation from organizations such as JCAHO or AAAHC prior to becoming contracted.

Financial Viability

As the first step in the EASC development process, it is recommended that you develop a comprehensive 5-7 year business plan assessing local expense factors (e.g., staff costs, building costs) as well as reimbursement projections. It is sound advice to be conservative in this exercise. A solid business plan is the basis for the best possible financing options from your local or national lender.

Organizing the Legal Structure

Rule #1 is to retain a qualified legal counsel experienced in ASC development transactions. Expect to incur significant legal costs as you set-up an appropriate legal structure. Strictly avoid engaging non-qualified firms—as is often true in life, you'll get what you pay for.

Rule #2 is to agree on all business terms among the owners before engaging counsel—don't let the lawyers negotiate your terms. Instead, focus the lawyers on crafting a solid operating agreement, medical staff bylaws etc as well written agreements will avoid many future frustrations.

Deciding Your Approach

There are three basic options to consider for developing your EASC. Each approach is different--carefully select the right fit for your group or coalition. The options are:

- *Do it yourself*—many groups have and are very satisfied; other groups have found this process to be frustrating, time-consuming and ultimately more expensive.
- *Retain a consultant*—there are some good ones out there that use two basic models. The options are:
  - pay a fee to build it, then the consultant goes away
  - pay a fee to build it, then the consultant charges a fee-based ongoing management fee annually
- *Join a corporate partner*—here there are two primary models to chose from:
  - The corporate partner has majority ownership & control

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ASCs Buying Pathology Services

ASCs and their partners are increasingly examining methods by which to profit from the provision of pathology services.

I. Overview and Summary Conclusions

In a typical arrangement between an ASC and a specific pathologist group ("Pathologists"), the ASC refers work to the Pathologists and the Pathologists bill the payor for the pathology services. Increasingly, centers propose to modify this structure as follows: the Center will refer work to the Pathologists, for which the Center will pay the Pathologists a predetermined discounted fee. The Center, and not the Pathologists, will then bill the payors for the pathology services.

Overall, this type of arrangement should arguably be legal as long as the Center, its owner physicians and their practices (1) do not send any federally funded or state public assistance patients to the Pathologists; (2) do not bill any patients or use this model for pathology services for which a federal or state program is the primary or secondary payor; (3) do not bill in a manner that is contrary to payor restrictions; (4) do comply with state law, and (5) do not allocate the right to bill to owners generally or in a manner that is based on volume or value of referrals. Finally, due to the changing nature of the manner in which regulations, laws and ASC requirements are applied, it is important that the Center have the right to terminate the arrangement at any time on very short notice. The Center should also assure that its liability insurance will cover incidents arising out of pathology services.

II. Stark Act

The Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn et seq. as amended (commonly known as the "Stark Act") forbids a physician from making referrals to an entity for any designated health service paid by Medicare, Medicaid, or other federal funds if the physician has a financial relationship with that entity. As long as no services referred to the Pathologists are paid by Medicare, Medicaid, or any federal funds and the Center does not bill for pathology services for any such referred services, the Stark Act should not be implicated. Here, we have discussed the requirement that the Center and its physicians will not refer any services paid for by federal or state funds to the Pathologists.

III. Anti-Kickback Statute

The federal Fraud and Abuse Statute, 42 U.S.C. § 1320a-7b(b) (the "Fraud and Abuse Statute" or "Anti-Kickback Statute") forbids payment or remuneration of any sort made to induce the referral of services paid for by Medicare, Medicaid, or other federal funds. Providing discounted services to a provider in hopes of gaining further referrals is a specifically enumerated "safe harbor" that is not forbidden by the Anti-Kickback Statute. See 42 C.F.R. § 1001.952(h). However, the Office of the Inspector General ("OIG") has

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made it clear that to provide a discount to some payors, but not to Medicare or Medicaid, is not a protected pricing structure. The situation described in OIG Advisory Opinion 99-13 provides a warning applicable to the structure proposed between the Center and the Pathologists. In that case, a physician group specializing in pathology services offered practices the ability to "buy" their services for a predetermined discounted rate The practices also referred their Medicare and Medicaid patients to the pathology group, but the pathology group billed Medicare and Medicaid themselves. The OIG determined that this structure was prohibited and that the groups could be subject to sanctions or exclusion from federal health programs. See OIG Advisory Opinion 99-13. To comply with the concepts set forth in this Advisory Opinion, the Center (and the physicians) must not refer Medicare, Medicaid or other federally funded services to the Pathologists.

The arrangement between the Pathologists and the Center would violate the Anti-Kickback Statute if any third party is induced to refer Medicare and Medicaid services to the Pathologists as a result of such arrangement, even though the Center has agreed that it will refer no Medicare or Medicaid services to the Pathologists directly. This inducement could relate, for example, to the physicians who own the Center. If a physician owner in the Center refers Medicare or Medicaid patients to the Pathologists in the course of his private practice based on the terms the Pathologists provide to the Center, this may be seen as an induced referral. To avoid possible investigation and prosecution, the physician owners of the Center should also not refer federally funded services to the Pathologists, even through their private practices.

IV. False Claims Act

The Center should bill all services in a truthful manner. Even if the services do not relate to federally funded patients, improper billing can create federal liability.

V. State Law

Many states have specific self-referral prohibition similar to the Stark Act. Many also have their own anti-kickback legislation. Any arrangement must be reviewed under state law as well. For the same reasons it is important that the Center not refer Medicare or Medicaid patients to the Pathologists, it is also important that the Center not refer to the Pathologists any Delaware public assistance program patients. Therefore, the Center will only conduct business with the Pathologists with regard to patients for which the Center will bill and will not send any other patients to the Pathologists.

VI. Payor Contracts and Third Party Billing

Before the Center provides billing for services performed by the Pathologists, the

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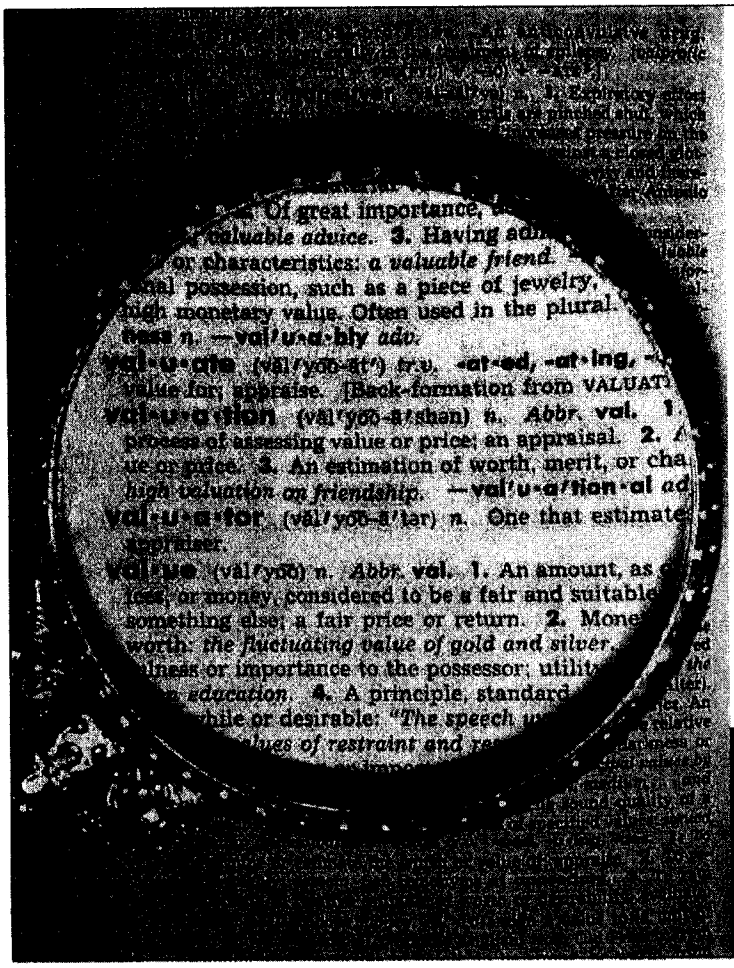
Center should carefully examine its contracts and agreements on billing practices with private insurers. These contracts may contain conditions or exclusions that prevent this new billing structure. For example, we need to assure that payors will allow the Center to bill for such services, and that there is not a restriction with such payors which would prohibit either buying services and rebilling the same or subcontracting for such services.

VII. Medicare Conditions of Coverage

As the Center is outsourcing this service and not directly providing it within the Center, this proposed arrangement should not violate the Medicare Conditions of Coverage for surgical centers. However, it is possible that surveyors or other authorities will question the arrangements. If this occurs, the Center will want to be able to cease such practice. ■



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- The corporate partner has minority ownership & the physicians have full control

Site Design Factors

There are a number of key questions that must be addressed when deciding where to locate your EASC:

- Will the facility be freestanding or attached to your professional practice office?
- Geographically speaking, where will the patients and physicians prefer to travel?
- Are there municipalities in the area where the permitting processes are more favorable to developing an EASC?
- Do you desire to purchase and build or would you prefer to fit-out an existing shelled space?
- How much space is required?

All states have there own set of guidance documents that regulate the physical plant codes that apply to developing your EASC. Some states require you to build an operating room, others do not. It's important to understand what codes apply to you—this is where selecting and contracting with a well qualified architect is critical. Select an architect who has successfully developed other EASCs in your region. The architect will be knowledgeable in the state specific interpretations of the physical plan codes as well as have strong relationships within the department of health.

In designing your overall floor plan, focus on patient flow and operational efficiency. Your architect knows the codes, but the obligation is upon you to determine flow patterns and preferences. We've found that investing substantial upfront time in developing your line schematics will quicken the overall pace of project as well as lower your own time investment in this phase. Once the line schematics are finalized, we strongly suggest scheduling a meeting with the architectural bureau within the state department of health to review the plan. We've found that obtaining this upfront "blessing" from state provides greater comfort to then engage the architect to complete the full set of architectural and engineering drawings.

We recommend engaging a general contractor well versed in EASC construction. A firm with general healthcare experience isn't specific enough to the particular nuances of the EASC niche. An experienced contractor has relations with the state that you can leverage to determine if the state will allow any variances or waivers within the EASC (e.g., if an OR is required, could the orbital lighting be eliminated based on intended use considerations).

Bid out the project to three or more general contractors. Your architect will assist you with developing the bid package—it's part of their standard suite of services. Your obligation is to fully understand what the contractor will be providing as well as what items you need to purchase separately—consider items such as the nurse call system, filing system, internal/external signage.

Closing Thoughts

A word to the wise, developing the facility is the easy part. Before you start your project it is critical to craft a detailed plan for providing on-going management for your EASC. A well thought out development plan along with a comprehensive management strategy should provide you with a highly successful EASC. ■