Joint ventures: A formula for successful arrangements

If your facility is involved in or considering entering into a joint venture agreement, you will likely face increasing legal risks in the current climate of increased scrutiny, said Bill Sarraille, Esq., a partner with the law firm of Sidley Austin Brown and Wood, LLP, in Washington, DC, during a recent audioconference.

As healthcare reimbursement has declined, utilization of imaging services has been on the rise. This has prompted increased suspicion by government enforcement officials that some of these imaging procedures may be more of a means to make money than a necessary step to help patients.

A series of cases highlighting illegal joint venture deals have made these imaging pacts a top priority for the Office of Inspector General (OIG).

But just because these agreements can be risky doesn’t mean that successful joint venture partnerships cannot be formed, Sarraille said.

Michael Manthei, a partner at the law firm Holland & Knight, LLP, in Boston, also spoke during the audioconference. He used several legal tests to assess whether a proposed arrangement should move forward. His analysis focused on the federal anti-kickback and Stark regulations, but he advised that you also look at your individual state regulations and other federal guidelines to ensure that your agreement is legal.

Performing the analysis

Case study: An equity joint venture between a hospital and a physician practice to establish a freestanding PET facility.

Manthei said there are two questions you should answer before you proceed with any deal:

1. What constitutes a joint venture?
2. What are the types of arrangements that might result in scrutiny by enforcement authorities?

“There is a tendency among people to look at joint ventures and think only about equity arrangements wherein the joint venture [partners] each own an equity interest in the operation of the joint venture,” Manthei said. “In reality the government has a much broader view of what constitutes a joint venture.”

The government considers a joint venture one that also includes contractual arrangements. This refers to any type of contractual arrangement in which the physician or other party will own or operate a facility or other type of venture. It can also be an alternate arrangement, such as hiring a
JOINT VENTURES (continued from p. 1)

physician or group practice to provide medical directorship and other administrative services, or compensating physicians to serve on advisory boards or other bodies (e.g., the board of directors, etc.).

Anti-kickback statute

Once a joint venture structure is proposed, the first statute that should be considered is the federal anti-kickback statute. This statute prohibits the payment, receipt, solicitation, or offer of any type of remuneration in exchange for the referral of items or services that could be reimbursed by any federal healthcare program.

The statute covers so much ground that almost any joint venture agreement between a hospital and a group of doctors will implicate the anti-kickback statute, said Manthei.

The question therefore becomes whether you can structure the arrangement to meet a “safe harbor” to the anti-kickback statute or, failing that, whether the arrangement contains safeguards against the abuses the statute is supposed to prevent. These include overutilization and interference with the professional decision-making process through the use of financial incentives.

Ask yourself: Are the joint venture partners in a position to refer business to the joint venture entity? In the case study proposed above, both the physicians and the hospital are likely in a position to refer patients to the joint venture. The hospital might exercise sufficient control or influence over staff and nonstaff physicians with privileges to influence their choices of PET facilities. Depending on their specialties, the physician joint-venture partners may be in a position to make direct referrals.

This doesn’t mean that the deal can’t move forward. One positive aspect of the anti-kickback statute is that it includes a number of safe harbors that were developed by the government. Safe harbors are areas that the OIG has identified as presenting a “minimal risk of fraud and abuse” and are therefore permissible under the law. “If you follow the requirements of a safe harbor exactly, the arrangement is deemed to be immune from prosecution,” said Manthei.

However, when it comes to this case study, there is no safe harbor that applies, said Manthei. At this point, the parties might want to consider an alternate structure (e.g., one that does not involve equity ownership by the physicians).

Safe harbors can protect several contractual relationships. For example, the safe harbor for personal services can protect an arrangement for the physician group to provide medical directorship and other administrative services. Similarly, the lease safe harbor can possibly be employed to protect an arrangement whereby the physicians own the land/building that houses the PET facility.

However, even if no safe harbor applies, it doesn’t necessarily spell doom for the deal. “There is a misconception in the industry that if you don’t meet a safe harbor, the arrangement automatically violates the anti-kickback statute or is otherwise illegal. That is really not the case,” said Manthei.

What it does mean is that enforcement authorities are going to look at all of the circumstances involved in the deal to obtain a true picture of
whether the arrangement is designed to induce referrals or if it presents a risk of fraud, said Manthei.

Keep in mind that the government will look beyond the documents. “You can’t paper over an otherwise inappropriate arrangement,” said Manthei. The government will follow the money regardless of how the documentation purports to structure the arrangement.

The litmus test
To determine the true intent of your deal, figure out what your goals are:
1. Are you trying to lock in referrals?
2. Are you trying to gain an economic advantage from the technical component of professional services that are rendered?

“If the answer to either of those questions is yes, then the arrangement likely will be viewed by the government as presenting a significant risk of fraud and abuse,” Manthei said. In that case, you must seriously consider whether to go forward with the proposed structure. This is also the time when alternate structures should be considered that might mitigate the government's concerns.

Analyzing Stark
The anti-kickback law isn’t the only regulation you need to worry about. The federal Stark law can also create problems for your agreements.

Stark prohibits self-referrals and prevents physicians from referring patients for a designated health service to an entity with which the physician or his or her close family member has a financial relationship. A financial relationship can range from ownership or investment interest to any other arrangement that provides compensation.

Currently, PET services, which are the focus of the joint venture in this case study, are not designated health services under Stark, but they are in the process of being added.

“No one really knows why [they were initially excluded]. I theorize that these services were really just emerging over the past several years as significant cost drivers in federal healthcare programs,” said Manthei. When the OIG defined designated health services, PET services may not have been significant enough to be included. In any event, it is clear that the government is poised to expand the definition of a designated health service specifically to include diagnostic and therapeutic nuclear medicine, including PET.

Because PET will be added to the list of designated health services, the joint venture outlined above in the case study will implicate the Stark law. If an arrangement does fall under the Stark provisions, it cannot move forward unless it meets the criteria for a Stark exception. There are several exceptions under Stark, all of which are fairly complicated, said Manthei. Unfortunately, there is no applicable exception for the equity joint venture outlined in the case study, so once PET is officially added to Stark, “you can’t do the deal,” Manthei said.

The risks of going around the law
Recently, investors in existing imaging centers have attempted to circumvent the Stark law prohibition on equity joint ventures by entering into various lease arrangements. These arrangements now are subject to the most intense government scrutiny. Prosecutors in Florida have already filed a case against a physician for participating in certain lease arrangements. That case still is pending.

In one type of leasing agreement, an imaging center charges physicians a low, flat fee per scan. Under this deal, the referring physician turns around and seeks a higher reimbursement rate from a private payer or the federal government. The referring physician doesn’t provide any real contribution to the delivery of the technical component service, other than his or her referral. The facility only leases the center to the physician when his or her patients are in the office, but not for a set block of time or on a weekly or monthly basis.

This type of deal raises serious legal questions, said Sarraille. But these deals are increasingly popular because they comply superficially with certain exceptions to the Stark law. This allows the referring physician to profit from his or her referral for a designated health service such as diagnostic imaging, which is already a designated health service, or PET, which will soon be a designated health service.

Attempting to circumvent Stark through these types of arrangements is particularly risky, given the current government scrutiny. Nevertheless, there are certain contractual joint ventures other than these lease arrangements that could pass muster under Stark.

Not all joint venture agreements pose the same degree of risk. If you perform a careful analysis of both the laws and your own motives, you can form successful and legal partnerships.

Editor's note: This story is based on HCPro's audioconference, “Risky Radiology Arrangements: How to Avoid Them and Create the Right Model for Success.” To purchase a copy, go to www.hcmarketplace.com or call the Customer Service Department at 877/727-1728.

Insider sources
Bill Sarraille, Esq., partner, Sidley Austin Brown and Wood, LLP, Washington, DC.
Michael Manthei, partner, Holland & Knight, LLP, Boston.
Numerous interventional radiology changes in CPT

By Jackie Miller, RHIA, CPC

There is one significant change for diagnostic radiology and numerous changes for interventional radiology in the 2006 edition of CPT®. I will discuss these briefly in this article and explore them in more depth in future issues.

Reconstruction

The new version of the CPT deletes code 76375 (coronal, sagittal, multiplanar, oblique, three-dimensional [3-D]/holographic reconstruction of computed tomography, magnetic resonance imaging[MRI], or other tomographic modality) and adds two new codes for 3-D rendering of tomographic studies:

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
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<tbody>
<tr>
<td>76376</td>
<td>3-D rendering with interpretation and reporting of CT, MRI, ultrasound, or other tomographic modality; not requiring image postprocessing on an independent workstation</td>
</tr>
<tr>
<td>76377</td>
<td>... requiring image postprocessing on an independent workstation</td>
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Two-dimensional reconstruction (e.g., reformatting an axial scan into the coronal plane) is now considered part of the tomography procedure and is not separately reportable. However, report 3-D reconstruction in addition to the tomographic exam using codes 76376 and 76377.

Do not report the new 3-D rendering codes. They, like the old reconstruction code, cannot be reported with magnetic resonance angiography or CTA because image post-processing is an integral part of the angiography procedure.

Mechanical thrombectomy

New codes have been added to CPT for mechanical thrombectomy in peripheral arteries and veins. Previously, there were codes only for mechanical thrombectomy of coronary arteries and dialysis fistulas.

The new mechanical thrombectomy codes are classified according to whether treatment occurs in an artery (new codes 37184–37186) or a vein (new codes 37187–37188). The arterial codes are classified according to whether mechanical thrombectomy was the primary means of treatment (37184–37185) or was performed in conjunction with another therapy, such as angioplasty (37186).

All of the new codes include fluoroscopic guidance, and there are no separate supervision and interpretation codes. However, code catheter placement separately. Similarly, code diagnostic angiography separately if it meets the criteria for a separate procedure (e.g., the patient has had no prior catheter angiogram).

Catheter check

There is also a new code for a contrast exam of an indwelling vascular catheter. Previously, there was no code for this procedure, so it was typically reported with the unlisted injection code (36299) in addition to fluoroscopy (76000) or
a venogram code, depending upon the documentation.

Note that the new code includes fluoroscopy, so do not report an imaging code with 36598 unless a separate diagnostic venogram is performed.

### Kyphoplasty

There are also new codes for kyphoplasty. Previously, this procedure was reported by physicians with code 22899 and by hospitals with codes C9718–C9719 (see the July 2005 RACRI).

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
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<tbody>
<tr>
<td>22523</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic lumbar</td>
</tr>
<tr>
<td>22525</td>
<td>... each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure).</td>
</tr>
</tbody>
</table>

Additionally, the guidance codes for vertebroplasty (76012–76013) have been revised, so they can be used with either vertebroplasty or kyphoplasty.

Note that the new kyphoplasty codes include bone biopsy by definition.

### Other changes

In addition to the changes discussed above, there are new and revised codes for the following procedures:

- Endovascular repair of thoracic aortic aneurysm
- Removal/replacement of ureteral stent
- Removal of nephrostomy tube
- Percutaneous radiofrequency ablation of renal tumors
- Intracranial stent placement
- Balloon dilation of intracranial vasospasm

Finally, some little-used nuclear medicine codes have been deleted (e.g., 78162, radioiron oral absorption).

Under the Health Insurance Portability and Accountability Act of 1996 transactions and code set standards, payers should accept the new and revised 2006 codes for services provided on January 1 and after.

Between now and January 1, providers should update their charge documents and train their coding and billing personnel on the new codes. Providers should also watch the CMS Web site (or the Federal Register) for the final 2006 Medicare regulations for hospital and physician payment, which will explain Medicare payment policy changes for 2006.

**Insider source**


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**Removing primary tumor may spur growth of metastases**

A new study shows that surgery to remove a primary breast cancer tumor may result in the formation of a new blood supply in metastases that were dormant, causing a cancer relapse, according to *Women’s Health Law Weekly*.

The study, published by the *International Journal of Surgery*, reviewed data from three clinical trials that involved women who had surgery for breast cancer, but no further treatment.

“Cancer outgrowth after surgery has been observed for over 100 years, and the mechanisms have not been fully identified,” researcher Michael Retsky, PhD, told *Women’s Health Law Weekly*.

“Our analysis suggests that biology may be the underlying cause, rather than something going wrong during surgery. It also suggest that [although] most young women benefit from early detection of breast cancer, a small percentage will relapse and die early of metastatic disease. The paper suggests remedial steps that might prevent the sudden growth from occurring.”

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Follow these four rules when faced with a lawsuit

By Frances C. Fenelon, Esq.

In the unfortunate event that a lawsuit is filed against your facility, you can take steps to protect it. Although some of the steps you take will vary depending on the nature of the case, there are several general rules you can follow. Remember the following four rules of thumb when faced with legal action:

1. Designate a gatekeeper.
   Assign one person in your facility to respond to—or redirect, if necessary—correspondence that may be related to a legal matter. This includes handling phone calls from attorneys, paralegals, other legal staff, private investigators, and insurance adjusters, as well as documents such as summonses, subpoenas, complaints, orders and other pleadings, and letters from attorneys or agencies, etc.

   Instruct all personnel to immediately direct these phone calls or other correspondence to the gatekeeper. Also develop a written policy that ensures prompt, adequate, and complete attention to the matter; avoids misunderstandings and interruptions of daily operations; protects the privacy of patients; and promotes the provision of quality healthcare.

   Note: An in-house attorney is the ideal gatekeeper. If none is available, ensure that the designated gatekeeper consults with outside counsel about the most appropriate methods for handling different types of callers and documents.

2. Discourage gossip.
   Instruct personnel and staff to discuss aspects of a dispute or controversy only with authorized individuals (e.g., peer-review process participants, management, etc.) and as needed (i.e., when it furthers a business or quality improvement purpose). In other words, discourage gossip. Most staff bylaws and facility policies, procedures, rules, or regulations include a confidentiality provision, and a written reminder is prudent when the rumor mill becomes exceedingly active. An informal reminder that lawsuits often include slander and libel claims against staff and employees is also effective in deterring needless chatter.

3. Preserve evidence
   Evidence is anything that is relevant to a claim or defense. This includes, but is not limited to, medical records, correspondence, memoranda, handwritten notes, videos, photographs, compact discs, e-mails, and electronic files.

   By law, you must preserve evidence not only with the initiation of a lawsuit but also when you could reasonably anticipate litigation (see note below). This obligation trumps any document destruction/retention policies. Consequently, when you anticipate legal action, distribute—tol anyone with access to potential evidence—written directions suspending relevant document destruction/retention policies and implementing a “hold” on relevant documents.

   Note: Like most aspects of the law, the issue of when someone should reasonably anticipate litigation is rarely black and white. Examples of when you should anticipate litigation include when a patient hires an attorney, as well as a statement by the patient mentioning the possibility of a lawsuit, litigation, legal recourse, or the exploration of all available options. Your safest bet is to ask an attorney.

4. Cooperate with your lawyer.
   It never ceases to amaze attorneys how often their clients are reluctant to work with them. More often than not, when people act under the misguided belief that involving a lawyer would only complicate matters, it leads to complications requiring much more significant legal intervention.

   Rest assured that your attorney takes no pleasure in your pain and will make every effort to make your life easier. Do not hesitate to contact your lawyer when a controversy that may reasonably lead to legal action arises, and consult with him or her before communicating, especially in writing, with a potential plaintiff.

Insider source
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Questions? Comments? Ideas?
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Q: Our facility recently purchased a PET/CT scanner. Many of the orders from our referring physicians request only a PET. Does the order need to specify PET/CT to perform and bill for a PET/CT?

A: According to the Society of Nuclear Medicine, facilities should not perform and bill for a PET/CT unless that imaging procedure is specified on the test order. It is recommended, however, that facilities take steps to educate referring physicians about the advantages of PET/CT over traditional PET scans so physicians order the most appropriate exam for the patient.

Q: What documentation is required to bill for a PET/CT and a diagnostic CT on the same day?

A: Any diagnostic CT exams performed on the same day as a PET/CT exam must be medically necessary and should be ordered by the referring physician. In addition, the facility must acquire a CT data set that is separate and distinct from the PET/CT. It must also document a written interpretation of the diagnostic CT exam in addition to the interpretation of the PET/CT exam. Remember to append modifier -59 to the CPT code for the diagnostic CT when submitting the claim.

Q: Can I bill for the fluorodeoxyglucose (FDG) radiotracer used during a PET scan?

A: According to the CPT manual, facilities should report diagnostic and therapeutic radiopharmaceuticals separately. In addition, CMS requires facilities to bill applicable tracer codes when submitting claims for a PET service. However, because charges submitted for either technical or global services for PET are carrier-priced, some Medicare contractors may choose to bundle reimbursement for the FDG into reimbursement for the PET procedure.

Q: What code should I assign for the FDG?

A: For claims submitted under OPPS, assign code C1775, supply of radiopharmaceutical diagnostic imaging agent, FDG F18 (2-deoxy-2-[18f]fluoro-d-glucose), per dose (4–40 mCi/ml). For all other claims submitted to a fiscal intermediary or carrier, assign code A4641, supply of radiopharmaceutical diagnostic imaging agent, not otherwise classified, for FDG.

Insider source
Stacie L. Buck, RHIA, LHRM, vice president, Southeast Radiology Management Corp., 512 St. Lucie Crescent, Stuart, FL 34994.
Billing: Positive digital mammography trial may pave the way for greater reimbursement

Until recently, the opinion of many private payers was that digital mammography provided no particular benefit to the patient. Therefore, payers reimbursed for it at the same rate as a film mammogram despite the additional cost—if they agreed to pay for digital exams at all, says Melody Mulaik, MSHS, CPC, CPC-H, RCC, of Coding Strategies, Inc.

However, since the release of the Digital Mammographic Imaging Screening Trial (DMIST), which found that digital technology is superior to analog when it comes to younger women or those with dense breasts, these billing policies may change.

Payers might rethink their past reimbursement policies now that there is a documented benefit to choosing digital over film technology, says Mulaik.

Medicare still uses G codes for direct digital mammography, a category that includes digital mammography equipment as opposed to items such as computer-aided detection equipment. The codes are as follows:

- G0202—Screening mammography producing direct digital image, bilateral, all views
- G0204—Diagnostic mammography producing direct digital image, bilateral, all views
- G0206—Diagnostic mammography producing direct digital image, unilateral, all views

When it comes to private payers, however, facilities that use digital equipment will likely have to contact each payer directly and ask which coverage it provides for digital mammography and which codes they should use for billing purposes. This can be done on a case-by-case basis or addressed during the contract process, says Mulaik.

“If payers will take [a G code] that’s great,” says Mulaik. However, if you use the old mammography codes, it will be a challenge to describe what you are doing.

The following steps can help you find the reimbursement and coding information you seek:

- First, check the payer’s Web site to see whether the information is posted.
- Then, talk to your payer’s representative and ask whether you can get the information in writing.
- If you can’t, draft a letter requesting the needed information and asking for the correct way to code this.
- Ask the medical director’s office for this information.
- If it doesn’t pay for digital mammography, you may be able to change its mind.

A matter of semantics

Two common phrases used by many radiologists include “compatible with” and “consistent with.” Coders have struggled with the meaning of those phrases. Should they be coded as definitive diagnoses?

Because no written guidance existed, many facilities have been left to decide for themselves how to handle these instances.

Many facilities opted to code these phrases as definitive diagnoses, and some formalized that decision in written policies.

Those facilities may have to change their practices. The most recent issue of Coding Clinic (third quarter 2005), published by the American Hospital Association, provides official coding advice on this issue, stating that these terms fit the definition of probable or suspected conditions.

Other phrases that fit this definition include “indicative of,” “suggestive of,” and “comparable with.”

You should not code diagnoses documented as “probable,” “suspected,” “questionable,” “rule out,” or “working.” Instead, code the condition(s) to the highest degree of certainty for that patient encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit, according to Diagnostic Coding & Reporting Guidelines for Outpatient Services.

Update all policies and procedures to reflect this current advice and educate all radiology coders on this issue.

Insider source
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