Heart Imaging Joint Ventures with Cardiologists: Why and How?

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Why Joint Venture With Cardiologists

As technological advances in non-invasive cardiac imaging begin to closely approach the efficacy and sophistication of the angiogram, business practices among cardiologists, radiologists and hospitals will need to evolve.

Over the past few years, cardiologists have become increasingly interested in the practical application of such imaging. It is far less invasive, less costly and more time efficient than the conventional angiogram. Additionally, as cardiac imaging has evolved to the point that it is now capable of producing high resolution, three-dimensional images of the heart that are comparable in utility to the results obtained from an angiogram, the test has experienced a significant surge in patient demand.

These factors have led many to conclude that non-invasive cardiac imaging could replace cardiac catheterization as the standard test for heart blockages. While the jury is still out on whether cardiac imaging can provide cardiologists with a detailed enough view of the coronary arteries to replace the tried and true methods of diagnosis, this is clearly the goal that the manufacturers are working toward.

The financial impact of this new tool, however, is forcing all stakeholders to reevaluate their core business models for the diagnostic component of cardiac care. Many radiologists view the advent of cardiac imaging as a win-win situation, capable of delivering highly accurate diagnoses with a less invasive process. But while they view the procedure as an opportunity to be involved in providing new professional services that offer an advancement in patient care, they are justifiably concerned about the financial and legal implications.

Firstly, interpreting diagnostic imaging requires specialized training that may be outside the scope of a cardiologist's expertise, meaning that a sizeable piece of income may be taken off of the table. Secondly, while the federal self-referral prohibition (the so-called Stark Law) generally does not apply to free-standing cardiac catheterization lab services, it does apply to diagnostic imaging services. This may cause problems for cardiologists who have used cath labs in which they have ownership. As a result, the cardiology profession is now faced with the challenge of developing a business structure that provides state-of-the-art patient care while keeping its doctors financially viable.

Structure Heart Imaging Joint Ventures

Radiologists, cardiologists and hospitals have an opportunity to form mutually beneficial partnerships that can both improve cardiac care and address the economic challenges. In order to be successful, however, these joint efforts must be carefully structured to comply with numerous laws. These include the Stark Law and state self-referral prohibitions, the federal anti-kickback statute, and analogous state laws, Medicare reimbursement requirements, certificate of need laws, and state licensure regulations.

Model One: Cardiology Group Exclusive Provider of Technical Component

The first model involves the *operation of the cardiac imaging equipment by the cardiologists*. In this model, the cardiology group practice exclusively performs the technical component of cardiac diagnostic imaging in accordance with the "in-office ancillary services" exception to the Stark Law. This exception allows physicians to refer for ancillary services, such as diagnostic imaging, to their group practice as long as certain requirements are met related to who provides and supervises the services, who bills for them, and the location at which they are provided.

Under this model, the cardiology group practice may provide the services in a centralized building or in the same building in which it maintains an office. Radiologists may read the cardiac images, but properly trained cardiologists are also permitted to perform these readings and be reimbursed for the professional component of the imaging service. Indeed, over time increasing numbers of the procedures will likely be read by cardiologists.

At first glance this model seems to provide a relatively simple solution for cardiologists. However, it does pose several challenges including making sure the location requirement under the in-office exception is satisfied, as well as the need to assess whether the cardiology group's utilization of the imaging equipment exclusively for its patients will justify the cost of deploying such expensive imaging equipment. This last issue is critical, so the cardiology group must have a strong sense for its anticipated utilization prior to implementing this model.

Model Two: shared imaging services only

A second model is sometimes referred to as the *shared imaging services* model. While this model may be set up in a number of different ways, the premise is that the cardi-

ology and radiology groups, possibly alongside other non-physician parties such as a hospital, establish a joint venture to act as an asset ownership company. The asset company purchases the necessary diagnostic equipment and provides whatever other imaging infrastructure is necessary to allow the cardiology group to be the technical component provider in accordance with the Stark Law in-office exception.

The asset company can also provide such infrastructure to the radiology group and other physician group practices to be the technical component provider to those groups' respective patients (also in accordance with the in-office exception). Imaging services ordered by the cardiology group, and any other group practice utilizing the infrastructure, are then billed by each practice under its provider number. The radiology group can provide the professional component, which can be billed by each group practice as part of a global charge (with each group practice paying a professional fee to the radiology group) or separately by the radiology group. Each group practice is responsible for paying the asset company an access fee for the imaging infrastructure. The access fee is structured to effectuate a sharing among all the group practices of the asset company's costs based on each practice's pro rata share of the asset company's fixed costs plus each practices' variable costs.

A significant regulatory consideration that the cardiology and other group practices must be aware of is the location requirement under the in-office exception. Because the asset company's infrastructure will not be utilized exclusively by the cardiology group, a centralized location cannot be used. Rather, the imaging services would need to be provided in the same building in which the cardiology group and each of the other group practices has its offices. Also, it would be important to pay attention to Stark Law rules which define when the imaging services can be used by group practices that only have part-time, instead of full-time, offices in the building.

Another consideration is Medicare's "purchased diagnostic test" limitation which essentially prohibits physicians from marking up purchased diagnostic tests. In particular, the relationship among the group practices that utilize the access company's infrastructure (and the access fee each practice pays) needs to be structured so that it will not constitute a "purchase" of diagnostic tests.

The principle benefit of this model is that the imaging infrastructure can be shared among multiple group practices, thereby making it easier to justify the cost of the equipment deployment. Also, patients benefit because of more convenient access to imaging services, i.e., patients from more group practices (other than just the cardiologists) can have their imaging services performed "right down the hall."

Model Three: Shared Imaging Services With IDTF

In a variation on model two, the third model would have the *asset company also acting as an independent diagnostic testing facility (IDTF)*. This means that in addition to providing the imaging infrastructure to the cardiology and other group practices, the asset company also provides diagnostic imaging to patients referred by physicians outside the building who have no financial relationship with the asset company. IDTF services generally are billed globally by the asset company under its IDTF number. As in the other models, the radiology group practice provides the professional component and receives a pre-negotiated professional fee.

This model encounters all of the regulatory considerations discussed above with respect to the other models. In addition, the asset company will have to apply to become an IDTF and then remain in compliance with the IDTF requirements.

This model expands upon the benefits of model two. With the asset company also able to act as an IDTF, it is less risky financially to incur the high costs of acquiring and developing the imaging infrastructure. In other words, this model furthers the risk-diversification strategy.

Model Four: Private Pay Only

The final part of the heart imaging business model is the *private pay only* model. Under this model, payment for heart imaging, as well as any other services provided utilizing imaging infrastructure, is sought solely from private, non-governmental payors, essentially eliminating Stark Law compliance requirements. Cardiology and other group practices who choose to go this route, however, must still be mindful of state self-referral laws and any applicable state "anti-brokering" prohibitions. Additionally, as with all models, the cardiology group and other group practices must ensure that private payors within the market will pay for services rendered by the practices.

Conclusion

Regardless of the advantages and drawbacks to each of these models, it is clear that non-invasive heart imaging is here to stay. Radiology groups, cardiology groups, and possibly other stakeholders such as hospitals should seriously consider how they can work together. In order to ensure a successful venture, though, it is critical to account for the numerous regulatory issues that must be addressed prior to beginning, as well as which model best utilizes the unique capabilities and resources each participant can bring to the table.

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