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Regulatory compliance and its effect on vendor-customer relationship

By *Steven R. Renard*

Understanding the rules and regulations as they apply to purchased diagnostic testing and professional courtesies is necessary if vendors are to appreciate the pressures that providers -- especially those in outpatient settings -- must face. In my experience as a consultant, I see vendors book orders that get canceled months later because their customer lacks the proper legal structure to qualify for Medicare's safe harbor rules.

Whether a site is a medical imaging, physical therapy, or outpatient surgery center, federal and state regulations apply, and operators must comply. Within these constraints, we must make purchasing decisions that affect our near- and long-term success. The seriousness of the situation has intensified with recent reimbursement cuts that have put radiology in the crosshairs of other medical professions in an unfortunate struggle for additional revenue generated from imaging procedures.

The roots of the current situation extend back to July 2004, when the Centers for Medicare and Medicaid Services published the Stark II regulations. These regulations define the legal relationship between radiologists and referring physicians. This legislation tightened the definition of "same building" as it pertains to the in-office ancillary services exception and offered new exclusions for purchased diagnostic tests and professional courtesy services. In my role as a consultant and outpatient imaging operator, I am amazed that almost two years later, confusion still surrounds those changes.

Purchased diagnostic testing: Stark II exempts arrangements that involve purchased diagnostic tests. To submit a clean claim for a purchased diagnostic test, the group practice must perform the professional component and cannot mark up the technical portion of the study. Conversely, the group practice may contract with a radiologist to perform the professional component.

An example of such an arrangement would be a cardiology

group and a radiology group entering into a written agreement for the cardiologist to purchase the technical portion of the test from the radiologist. The radiologist can perform the professional interpretation and reassign billing to the cardiologist. The cardiologist can, in turn, bill for both the technical and professional components.

Consequently, vendors should be aware of how specialists such as cardiologists set up their practices and of the laws that govern those practices, as these circumstances will likely affect their ability to sell equipment.

Such arrangements should offer protection through the purchased diagnostic test exception. Some states, however, have attempted to enact their own rules banning these leasing arrangements.

Professional courtesy: Another area of confusion is professional courtesies. Many centers find themselves having to say "no" to their top referring physicians, because they fear repercussions from CMS and the Office of the Inspector General. This fear, coupled with referring physicians who lack an understanding of or don't sympathize with a center's legal obligations to comply with professional courtesy standards, can often result in a misperception about the center's role. While centers strive to be helpful and accommodating, at the same time they must adhere to legal guidelines.

Vendors should review a center's policies regarding professional courtesy to avoid conflicts during the center's applications period, when it is likely to offer exams for which it doesn't charge to the community. It is also important to note that noncompliance will affect the financing vendor indirectly in the event monetary sanctions are imposed on the center.

Back in July 2004, Medicare cracked the door open ever so slightly and established several new expectations surrounding professional courtesies. This exception provided centers the option to either decline or accept all professional courtesy arrangements. The newer language allows for professional

courtesies to exist in a restricted environment. Nonetheless, the arrangement must meet the following CMS criteria:

- The service must be offered to all the physicians on staff or in the imaging center's local community without regard to the volume or value generated from the referring party to the center.
- The policy must be spelled out in writing by the governing body of the healthcare provider.
- The imaging service cannot be offered to a physician or immediate family member who is the recipient of a federal healthcare program, unless financial hardship has been proven.
- The types of imaging services being offered as courtesies are routinely provided by the center.
- The professional courtesy service being offered must not violate current antikickback statutes or any claims submission laws.
- If the professional courtesy service involves a whole or partial waiver of coinsurance, the payer must be informed in writing so that it is aware of the reduction.

The OIG notes two important factors to keep in mind, when considering whether a professional courtesy program is running amok. The OIG looks first at how the recipients of professional courtesies are selected and second at how the professional courtesies are extended. Essentially, a center that

extends professional courtesies only to its "top referrals" is considered to be in violation. Additionally, taking "insurance only" is not viewed as a loophole -- in fact, it can be considered an inducement and may violate the Civil False Claims act.

In summary, it is very important that an operator obtain the proper legal advice when establishing timed-leased arrangements and professional courtesy programs and when developing joint-venture relationships within specialties, such as orthopedics or cardiology. It is the responsibility of the center operator to ensure that the arrangement is legal because the penalties for accepting a prohibited referral are imposed on the center or radiologist, not the referral source. The cost of these penalties can be fairly hefty and include repayment of claims for services provided and civil and monetary penalties for those who knowingly violate Stark regulations.

Vendors can help by knowing and then educating providers on the do's and don'ts of Stark regulations prior to signing quotes. Directing a customer to a healthcare attorney or providing him or her with written legal opinions can assure that an operator get off the ground and deals stay booked.

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