Ambulatory surgery centers: Five common compliance myths

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W hile the federal physician self-referral statute (commonly known as the Stark law) has significantly restricted the feasibility of many traditional, free-standing physician joint ventures, it has had no such effect on ambulatory surgery centers (ASCs). Subject to certain exceptions, the Stark law prohibits physicians from referring Medicare patients to an entity for certain “designated health services” if the physician has a financial relationship with that entity. ASC services are not, themselves, “designated health services” covered by the Stark law; thus, there are no Stark-based limitations or restrictions on physician ownership of ASCs, as long as the ASC does not provide any separately billable designated health care services. In other words, any “designated health services” (such as clinical laboratory services or outpatient drugs) provided by the ASC must be included within the ASC’s composite rate payments, not billable to Medicare separately.

Accordingly, there has been a considerable amount of activity surrounding ASCs, including a proliferation of ASC joint ventures of all kinds, especially joint ventures between physicians and a local hospital or health care system. Because ASC joint-venture deals involve a variety of complex legal and regulatory issues, several common compliance myths have emerged. This article addresses the “top five” compliance myths surrounding ASCs.

Myth One: It is “too risky” to be outside the safe harbor

Although the Stark law does not apply to ASCs, the federal Anti-kickback Statute does apply. The Anti-Kickback statute prohibits any person from “knowingly and willfully” providing any remuneration to induce referrals, or in exchange for referrals, of federal health care program patients or business. Accordingly, the Anti-kickback Statute applies to any physician-owned ASC that treats federal health care program patients (including Medicare and Medicaid), in that the potential return on investment, arguably, could be viewed as an inducement for physician investors to refer to the ASC.

However, there is an ASC “safe harbor” under the Anti-kickback Statute, which protects various types of physician-owned ASCs as well as hospital/physician ASC joint ventures. The hospital/physician ASC safe harbor protects joint ventures that have one or more hospital investor, when all the physician investors meet specific requirements (they must be physicians in a position to refer to and perform procedures at the ASC, and derive at least one-third of their practice income from the performance of these procedures, or they must not be in a position to refer at all), if the ASC satisfies eight criteria:

1) Terms on which investments are offered.
2) The ASC or any investor (or anyone acting on their behalf) may not loan funds or guarantee any loan to an investor if the loan proceeds are used to purchase the investment.
3) The return on investment must be directly proportional to the amount of capital invested.
4) The ASC and its hospital and physician investors must treat patients receiving medical benefits or assistance under any federal health care program in a non-discriminatory manner.
5) The ASC may not use hospital space, equipment, or services unless it meets the requirements, respectively, of the space, equipment or personal services safe harbors.
6) All ancillary services provided at the ASC must be directly and integrally related to primary procedures provided there, and none may be separately billed to the Medicare or Medicaid programs.
7) The hospital may not include on its own cost report or claim for payment of any costs of the ASC, unless it is required to do so.
8) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity (for example, by having physician employees or owning a medical practice). Also, patients referred to the ASC by a physician investor must be fully informed of the referring physician’s investment interest.

If the ASC satisfies all the elements of the safe harbor, then the profit distributions from the ASC to its investors are protected from both criminal prosecution and civil penalties under the Anti-kickback Statute. Failure to satisfy the safe harbor does not mean that the ASC joint venture is necessarily illegal, but rather that it may be subject to scrutiny and prosecution.

It is important to recognize that many ASCs with physician investors do not meet the safe
harbor require. While there is no immunity for “substantial compliance” (i.e., operating as close to the safe harbor as reasonable and practical), it is widely believed that ASC joint ventures that are appropriately structured and operated should have reasonably low risk under the Anti-kickback Statute, even if they do not come squarely within the safe harbor. This view is based, in part, on the only federal court case that analyzes the application of the Anti-kickback Statute to joint ventures. That court concluded that a physician’s ownership interest in a health care provider does not violate the Anti-kickback Statute so long as:

- the return on investment is based on each physician’s ownership interest and not their referrals,
- eligibility to invest does not depend on an agreement to refer,
- the size of the investment is not based on referrals, and
- physicians who do not refer are not required or pressured to divest.

Myth Two: Primary care physicians cannot invest in an ASC

This myth is a corollary of the first one, and stems from the common misperception that coming within a safe harbor is essential (or very nearly so). In truth, although ASCs that have primary care physicians as investors cannot qualify for the ASC safe harbor, this does not mean that primary care physicians are “prohibited” from investing in an ASC. As explained above, the safe harbors are voluntary, not mandatory, and the failure to satisfy a safe harbor does not mean that an arrangement is necessarily illegal, only that it may be subject to scrutiny and potential prosecution.

In fact, very few arrangements between, for example, hospitals and physicians, can satisfy a safe harbor, whether these arrangements entail ASC joint ventures, leases, medical director agreements, or recruitment arrangements (with the exception of employment arrangements and managed care contracts, both of which have broad safe harbors). Like these other arrangements, if the ASC joint venture is appropriately structured and operated (e.g., among other things, it follows the guidance found in the federal court case, mentioned above) it should have reasonably low risk under the Anti-kickback Statute, even if it does not come squarely within the safe harbor.

Additional steps to consider in limiting risk under the Anti-kickback Statute include:

- The investment terms should be the same for all investors, regardless of referrals, and the return to investors should be based on ownership interests, not on referrals. (To further reduce risk, all physician investors could own equal shares).
- The physician investors should also be paying fair market value (which could be verified by an independent-expert valuation appraiser) for their investment interests in the ASC. The ASC should pay fair market value for any space and employees it leases and for any management services it purchases from referral sources. These rental and compensation payment amounts also could be verified to be fair market by one or more independent-expert valuation appraisers.
- Any non-compete provisions in the ASC’s governing documents should be limited so that they specifically permit the physician investors to refer to any other facility. In fact, there should be no requirement, express or implied, that physician investors must refer to the ASC or remain in a position to refer to the ASC as a condition of continuing to retain their investment interests.

Myth Three: Physicians can and should be required to perform procedures at the ASC

One additional wrinkle to the ASC safe harbor is that multi-specialty physician-owned ASCs can qualify for the safe harbor only if the physician investors (other than those who are not in a position to refer) perform at least one-third of their total Medicare-covered ASC procedures at the ASC in which they have an investment interest. Consequently, these ASCs might consider whether they should require (i.e., in the ASC’s governing documents) physician investors to perform at least one third of their ASC procedures at that ASC, and compel divestment if the physician fails to meet this requirement, to ensure compliance with the safe harbor. Some health care lawyers believe this approach is advisable, or at least permissible.

However, some courts have found that when remuneration, which includes the opportunity to earn money from an investment, is explicitly conditioned on referrals, then the Anti-kickback Statute is violated. Thus, if a multi-specialty physician-owned ASC were to require physicians to perform at least one third of their procedures at that ASC, and then attempted to divest a physician who failed to meet that requirement, the ASC potentially could be challenged for directly linking remuneration to continued referrals.

Myth Four: If you’re in the safe harbor, you have no other compliance concerns

Meeting the safe harbor requirements does not exempt providers from ensuring compliance in other areas, and they should be mindful of issues regarding medical necessity and quality of care. The law imposes specific and extensive obligations on all providers for ensuring that services are supported by evidence of medical necessity and executed under adequate standards of quality assurance.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposed civil monetary sanctions focused on lack of medical necessity, with penalties up to $10,000 per claim, for a pattern of medical or other items or...
services that a person knows or should know are not medically necessary. Furthermore, federal law imposes obligations on all health care practitioners to ensure that services or items ordered or provided by such practitioners will be:

- provided economically and only when, and to the extent, medically necessary,
- of a quality which meets professionally recognized standards of health care, and
- supported by evidence of medical necessity and quality in such form and fashion as may be required by peer review organizations.

Services proven to be medically unnecessary or deficient in quality of care assessments not only risk failing to meet federal and third-party reimbursement requirements, but could also potentially subject an ASC to liability under the False Claims Act. Recent theories hold that seeking payment from the government (e.g., Medicare) for unnecessary or substandard patient care is tantamount to submitting false claims, in violation of the federal False Claims Act.

One way to limit such risk is to engage an independent medical review expert to confirm the quality and medical necessity of any services provided by the ASC, once it begins operations, and periodically thereafter. Likewise, a retrospective review could be done to confirm that the nature and amount of procedures ordered by the physician investors has not changed since they became investors.

Myth Five: Tax exempt hospitals must own a majority of the ASC

One final myth applies to ASC joint ventures between tax-exempt hospitals and physicians. This myth, that the hospital must own a majority of the ASC, arises from a 1998 revenue rule issuance, and the IRS litigation position in Redlands Surgical Services v. C.I.R. The IRS created quite a stir by asserting that in order for the conduct of a hospital/physician health care joint venture to be in furtherance of tax-exempt purposes (and therefore not give rise to unrelated business income), the hospital needed to control the venture at a governing board level. The IRS posted in Redlands that without control over joint-venture operations, there could be no assurance that the venture would be operated in a charitable manner.

However, in Rev. Rul. 2004-51, the IRS backed-off this position somewhat by holding that, in a joint venture between a university and a for-profit company to make and market video educational courses, the university’s share of joint-venture income was not unrelated business taxable income. Even though the university did not control the venture at a governing board level, it controlled the educational content and standards of the video that the venture produced. It is somewhat difficult to translate the standards of Rev. Rul. 2004-51 to a health care joint venture context. However, by controlling those aspects of the joint venture bearing upon its charitable, the hospital should have a good position that its share of venture profits are not unrelated business taxable income. Such areas of control include sufficient authority to ensure that:

- privileges to use the ASC are available to all qualified practitioners in the community;
- the ASC provides a minimum level of care to indigent patients (the ASC’s adoption and observance of the hospital’s charity care policy should be sufficient in this regard);
- the ASC accepts Medicare patients (and some level of Medicaid patients); and
- the ASC is available to all in the community who are able to pay its established charges, whether through governmental payment programs, private insurance, or otherwise.

Although control at a governing board level (by appointing a majority of the members of the governing body) will assure sufficient control to avoid unrelated business income treatment, in the absence of majority board control, the above elements of control, arguably, should be sufficient.

Conclusion

The prospect of forming a physician or a hospital/physician ASC joint venture can be daunting given the myriad of complex business, legal, and regulatory compliance issues that arise; however, these issues are made even more difficult by the prevalence and persistence of several common compliance myths. By dispelling these myths, and engaging in solid strategic planning and sound execution, your ASC joint venture can be successful and compliant.

For advice on specific situations, always consult legal counsel in your state.

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