When was the last time you considered investing, or renting space, in an ambulatory surgery center (ASC)? While issues of whether the transaction makes good business sense are, naturally, at the forefront of any business person’s mind, often physicians (including anesthesiologists) fail to take into account the compliance considerations that are the drivers of many of the underlying business decisions. Unfortunately, in today’s healthcare regulatory arena, no anesthesiologist can ignore the importance of ensuring compliance with State and Federal Laws when considering a relationship with an ASC.

For purposes of this article, an ASC is a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed twenty-four hours following an admission. The entity must have an agreement with the Centers for Medicare and Medicaid Services to participate in Medicare as an ASC, and must meet the conditions of participation and conditions of payment set forth by regulation.

**I. First Things First**

There are many ways in which becoming an owner or investing in, or renting, an ASC comes to fruition. The business decisions that will undoubtedly face any prospective purchaser or lessee are beyond the scope of this article, though it goes without saying with every transaction must come thorough due diligence. Although much of the focus of any deal is a numbers game, considering the compliance implications of those numbers is critical prior to investing in, or renting, an ASC.

One key compliance-related matter tied to due diligence is investigating your potential partners. This is an easy element to overlook and one that, if not properly investigated, will lead to considerable government exposure. The government considers individuals who contract with excluded providers or those without licenses one of the easiest targets in their fight against healthcare fraud. Therefore, it is critical that, prior to entering into any transaction, while due diligence is being conducted on the business itself, due diligence is conducted on the people involved in the transaction. In other words, it is just as important to investigate your partners’ backgrounds, as it is to investigate the viability of the business in which you may be investing or from which you may be leasing. Such checks are relatively simple and involve looking at websites such as the OIG’s list of excluded providers and state licensing board sites. These are some of the easiest, and least expensive, methods of protecting one’s self in a transaction as discovery by government enforcement is all too easy. It does not require an attorney to run a Google search, an exclusion check, or a licensure check.

Concurrent with due diligence investigations, when considering transactions involving ASCs, all parties involved should consider whether, and how, the federal Anti-Kickback Statute (AKS), federal Physician Self-Referral Law (Stark Law), and relevant State laws affect the manner in which the transaction may commence. These laws underlie every transaction in the healthcare industry and, while they may not necessarily be implicated, must always be taken into consideration.
The AKS prohibits the knowing and willful soliciting, receiving, offering, or paying of remuneration (which is anything of value, in cash or in kind) to induce referrals of items or services payable by any State or Federal healthcare program. It has been interpreted by courts (and the Office of Inspector General (OIG)) to the effect that if even one purpose of the transaction is to promote referrals, the entire transaction is unlawful, despite any other proper purposes that may exist. Violation of the AKS could result in civil penalties, criminal penalties, fines, prison time, exclusion from any State and/or Federal healthcare program, and/or loss of state licenses. The AKS has a number of safe harbors that, if an arrangement fits squarely within, are presumed by the government to be lawful. Failure to fit within a safe harbor, however, does not make the arrangement unlawful; rather, it requires an analysis of the specific facts and circumstances at hand.

The Stark Law prohibits referrals by a physician (note: the AKS does not require the referral to be from, or to, a physician) for certain designated health services (DHS) to a person or entity in which that physician has a financial interest, unless an exception applies. DHS includes (1) clinical laboratory services, (2) physical therapy services, (3) occupational therapy services, (4) outpatient speech-language pathology services, (5) radiology and certain other imaging services, (6) radiation therapy services and supplies, (7) durable medical equipment and supplies, (8) parenteral and enteral nutrients, equipment, and supplies, (9) prosthetics, orthotics, and prosthetic devices and supplies, (10) home health services, (11) outpatient prescription drugs, and (12) inpatient and outpatient hospital services. Financial relationships include ownership or investment interests or other compensation arrangements. Violation of the Stark Law could result in civil penalties, program exclusion, the implication of other civil or federal laws that carry with them other hefty fines, and/or loss of state licenses. In contrast to the seeming flexibility afforded by the AKS, the Stark Law is more rigid. The Stark Law has a number of exceptions that, an arrangement failing to fit squarely within, will be considered unlawful, without further evaluation.

By providing anesthesia services alone, an anesthesiologist does not make a referral for a DHS and does not come within the Stark prohibition on self-referral; nor does the provision of anesthesia services without more entail a referral for purposes of the AKS. Pain medicine services are subject to a different analysis because pain specialists do refer patients for PT or radiology services, for example. Every assessment of anesthesiologists’ Stark or AKS exposure begins with the question whether the anesthesiologists are referring patients to others or whether the patients are being referred to them.

II. Renting Space in an ASC

Renting space in an ASC carries with it its own AKS safe harbors and Stark Law exceptions with which anesthesiologists must comply in order to avoid violations. In this case, because the requirements of the AKS safe harbors for the lease of space, the lease of equipment, and personal services are similar to the requirements of the Stark Law exception, if the Stark Law is implicated, there is little no flexibility in whether to comply. Remember: if implicated, compliance with a Stark Law exception is mandatory or else the entire relationship is unlawful. If the Stark Law is not implicated, there is some flexibility in whether the parties wish to set the relationship squarely within the AKS safe harbor. Of course, the closer a transaction is to a safe harbor, the less it is exposed to risk; however, transactions not fitting within a safe harbor are not necessarily considered illegal.

If the parties desire to structure the transaction to fit squarely within the safe harbor for equipment and space rental or personal services, it must satisfy the following requirements:

1. A written, signed agreement must be in place between the parties;
2. A lease covers all of the premises, equipment, or services involved for the term of the lease and specifies the premises, equipment, or services covered by the agreement;
3. If the arrangement is for a part-time basis (versus on a full-time basis), the agreement specifies exactly the schedule of such intervals, their precise length, and the exact compensation for such intervals;

4. The term of the lease is not less than one year;

5. The aggregate amount paid under the agreement is set in advance, consistent with fair market value in an arms-length transaction and is not determined in a manner that takes into account the volume or value of referrals or other business generated by the relationship for which payment may be made in whole or in part under State or Federal healthcare programs;

6. The aggregate space, equipment, or services do not exceed that which is reasonable necessary to accomplish the commercially reasonable business purpose for the rental.

For purposes of these safe harbors, *fair market value* means the value of the rental property, or equipment, for general commercial purposes, not adjusted to reflect the additional value that one party would attribute to the property as a result of the transaction.

If parties desire to structure a transaction that does not fit within a safe harbor, depending on the facts and circumstances at hand, a number of mitigating factors may be incorporated to minimize the amount of overutilization of services payable by the State and Federal healthcare programs. The OIG regularly issues advisory opinions in which it provides guidance on satisfactory mitigating factors relative to various arrangements.

**III. PURCHASING, OR SELLING, AN ASC**

In purchasing or selling an ASC, the foundational compliance issues that must be taken into consideration are (a) whether the purchase price represents fair market value, and (b) whether there is a commercially reasonable business reason for the transaction.

The definition of fair market value in the business world is considered the price when there exists a hypothetical willing, able, and informed buyer and a hypothetical willing, able, and informed seller, acting at arms-length in an open and unrestricted market, when neither is obligated to buy or sell. Fair market valuations can take into account historical earnings, contracts with third party payors, certificate of needs laws and can be conducted by certain accounting firms with specific healthcare knowledge and experience. Commercial reasonableness hinges on whether the transaction makes sense if referrals were not part of the picture.

When considering whether or not to purchase an ASC, the purchaser should consider, and understand, the specialties of any other physician owners involved in the ASC as the requirements for satisfying the AKS safe harbors for ASC ownership and investment vary depending on whether the owners are all physicians or comprised of multiple specialties or if the owners include a hospital. The requirements of this safe harbor are considered in Section IV of this article.

**IV. OPERATING THE ASC**

After considering the foundational compliance issues noted above, there should be consideration given to whether the transaction should (and whether the parties desire for the transaction to) meet the AKS safe harbor for ASC ownership. The path of least risk would involve having the ownership or investment fit squarely within the ASC safe harbor.
Such arrangements falling outside of a safe harbor should be carefully structured with the assistance of an attorney.

For all ownership or investment interests in an ASC, the ASC’s operating room and recovery space must be dedicated exclusively to the ASC. Patients who are referred by an investor in the ASC must be fully informed of the investor’s investment interest. As mentioned in the previous section, there are also requirements of the ASC safe harbor that vary depending on the identity of the owners of the ASC. For purposes most germane to anesthesia, this article only reviews the requirements for multi-specialty ASCs and hospital-physician ASCs (the other considerations of the ASC safe harbor include surgeon-only ASCs and single-specialty ASCs).

A. Multi-Specialty ASCs

For purposes of the safe harbor, multi-specialty ASCs may be owned by (i) physicians in a position to refer patients directly to the ASC and perform procedures on such patients; (ii) group practices composed exclusively of physicians; or (iii) investors who are not employed by the ASC or by any investor and are not in a position to provide items or services to the ASC or any of its investors and are not in a position to make or influence referrals to the ASC or any of its investors. Assuming the owners fit one of the aforementioned categories, to satisfy the safe harbor, anesthesia investors must meet the following seven elements:

1. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the ASC.
2. At least one-third of each physician investor’s medical practice income from all sources for the previous fiscal year or previous twelve month period must be derived from the physician’s performance of Medicare-covered procedures for ASCs.
3. At least one-third of the Medicare-covered procedures for ASCs performed by each physician investor for the previous fiscal year or previous twelve month period must be performed at the investment entity (i.e., the ASC at issue).
4. The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.
5. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.
6. All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.
7. The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

Elements 2 and 3 comprise what is commonly referred to as the One Third-One Third Test.

B. Hospital-Physician ASCs

ASCs owned by hospitals and physicians (including anesthesiologists) must be owned by at least one hospital investor and (i) surgeons, physicians of a single-specialty, or physicians comprising multiple specialties; (ii) group practices; or (iii) investors who are not employed by the ASC or by any investor, are not in a position to provide items or services to the ASC or any of its investors, and are not in a position to refer patients.
THINKING OF INVESTING IN, OR RENTING SPACE IN, AN ASC?
HAVE YOU TAKEN COMPLIANCE INTO CONSIDERATION?

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directly or indirectly to the ASC or any of its investors. Assuming the ownership requirements have been met, for anesthesiologists looking to be owners or investors in an ASC alongside, at least, a hospital, the following nine elements must be satisfied:

1. The One Third-One Third Test must be satisfied for each physician owner.
2. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.
3. The ASC or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.
4. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.
5. The ASC and any hospital or physician investor must treat patients receiving medical benefits or assistance under any federal health care program in a nondiscriminatory manner.
6. The ASC may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor (explained in greater detail in Section II of this article); nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor (explained in greater detail in Section II of this article), and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor (See 42 CFR 1001.952(d)).
7. All ancillary services for federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity and none may be separately billed to Medicare or other federal health care programs.
8. The hospital may not include on its cost report or any claim for payment from a federal health care program any costs associated with the ASC (unless such costs are required to be included by a federal health care program).
9. The hospital may not be in a position to make or influence referrals
directly or indirectly to any investor or the entity.

As can be seen with both of these ASC safe harbors, the key issue on which anesthesiologists must focus is the One Third-One Third test. In fact, it is in every ASC owner’s interest to ensure all physician owners are satisfying this requirement as one person who is non-compliant precludes the entire arrangement from fitting squarely within the safe harbor. It is important to note that some courts raised issues of directly linking remuneration to referrals when ASCs had a specific and explicit requirement that physicians perform at least one third of their procedures at the ASC.

C. Other Operational Considerations

While beyond the scope of this article, other operational considerations must be given to the relationship between the parties of an ASC. Namely, the business models that may be adopted to operate the ASC may be considered with their respective risks and benefits. Such business models may include:

- The Service Agreement Model—This model involves an ASC contracting with an anesthesiologist or anesthesia group in which the ASC provides office space, equipment, and administrative support to the anesthesia providers in exchange for a fee.
- The Endoscopy Suite Model—This model involves gastrointestinal physicians setting up a surgical practice in an office-based setting in which they obtain the space, personnel, and accreditation for the facility. This space is then, in turn, subleased to the anesthesiologists who also contract for equipment and administrative support in exchange for a fee.
- The Company Model—This model involves the owners of the ASC developing a separate company (NewCo), owned by the owners of the ASC, that is formed to provide anesthesia services to the ASC. NewCo then contracts with anesthesiologists or an anesthesia group either as employees or independent contractors. The excess profits earned by NewCo, which bills for the anesthesia services, after paying the anesthesiologists, then flow back to its owners.
- The Employment or Independent Contractor Model—This model involves the ASC directly hiring the anesthesiologists as employees or independent contractors.

Other considerations must also take into account in a sale include whether federal securities laws are implicated and whether the transaction is subject to registration and disclosure requirements.

V. All Transactions are Unique

Although the compliance issues raised in this article raise a number of considerations when anesthesiologists are looking to invest, or rent space in, an ASC, it is important to recognize that each and every transaction is unique and each requires its own analysis. While no transaction is devoid of all risk, the owners or prospective-owners or lessee should engage competent counsel to assist in analyzing the risk associated with a given transaction. Failure to take compliance into consideration in such an arrangement could result in substantial fines, potential prison time, exclusion from state or federal healthcare programs, and potential loss of license.

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