

Ambulatory Surgery Center (ASC) Compliance Issues

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Ambulatory surgery centers (ASCs) are often used in place of having a surgery in a hospital. There are many advantages that the owners of these facilities tout and the doctors and patients who have surgeries there praise. These benefits include:

- **Better outcomes.** Generally, the surgeries are shorter, the recovery times are faster, and the rate of infections as compared to hospitals is almost twice as low when the ASC is used for the operation. As a general rule, patients who have a surgery at an ASC also do not need as much hospital follow-up.
- **More practical.** The waiting time and processing time at an ASC is usually shorter than for hospital surgeries.
- **Lower costs.** The cost of an ASC surgery is half as much as a hospital procedure. These savings help not only the patient but private insurers and taxpayers who help fund public health programs such as Medicare. DHHS estimates that taxpayers save \$15 billion and Medicare patients save \$3 billion from ASC use. While the costs are lower, the quality of care is generally comparable to hospital surgeries.
- **Better individual service.** Since the focus of an ASC is just on the surgery, the time to schedule appointments is generally much better. In many cases, the doctors and staff provide more personalized care and follow-up than hospitals do.

In 2014, surgeries at ASCs accounted for nearly 66% of all surgeries.

ASCs are subject to regulations by the federal and state agencies especially when the ASCs treat patients who use Medicare or Medicaid – which is virtually true for all ASCs. Some of the compliance issues which an experienced healthcare lawyer can explain and can help you prepare compliance for are the following:

The Anti-Kickback Statute and Stark law

The federal Anti-Kickback Statute and Stark law both regulate the ways in which doctors and medical practices can make referrals of patients and also receive referrals. The aim of both is to ensure that referrals are based on what is best for the patient and not what is best for the financial well-being of the doctor/medical practice.

The Anti-Kickback Statute prohibits doctors from receiving, offering, paying, or accepting any form of remuneration in return for obtaining a referral. Remuneration includes financial payments, sham directorships, expensive lunches and vacations, paying for medical equipment, or most anything of value.

Stark Law provides that doctors cannot refer patients to any designated medical health service in which the doctor, medical practice, or immediate family members has a financial interest in. An ambulatory surgery center is a classic example of a designated medical health service.

The AKS allows for safe harbors which can reduce the risk of an AKS complaint. Similarly, Stark Law has a list of predefined exceptions which, if properly created, can work as a defense to any claim the medical provider violated Stark Law. At the core of these safe harbors and exceptions are that the relationships:

- Should be in writing
- Should be based on fair market value
- Should not be based on the volume or quantity of referrals
- Other factors that depend on the type of business relationship

EXCEPTIONS TO THE STARK LAW PROHIBITION OF MEDICAL REFERRALS

The Stark Law governs what types of referrals doctors can make if they bill for Medicare and Medicaid. The presumption is that that referrals made by a doctor to a designated health service are [...]

The government is spending more money and time on prosecuting medical fraud. Violations of the AKS and of Stark Law are also considered violations of the False Claims Act (FCA). The FCA encourages employees, vendors, contractors, and partners to disclose kickbacks and illegal referrals. In return, these whistleblowers are paid a percentage of the recovery. The penalties for violating these laws can result in severe civil penalties, statutory fines, orders that the medical practice be prohibited from billing Medicare and other federal health care agencies, interest, and legal fees. The AKS is a criminal statute which means violations can result in prison time.

Doctors, labs, testing facilities, ASCs, and other healthcare providers and health companies need to consult with experience AKS and Stark Law attorneys who can give advice on the legal issues and the ways to reduce the risk of criminal and civil charges.

Some of the areas that are red flags for ASCs include selling shares in the ASC to doctors at below fair market value, leasing equipment at below fair market value or on a per-click basis, and the use of sham directorships, and other types of misconduct.

Additional ASC financial relationship concerns that may run afoul of the AKS or Stark Law include:

- **Junior physicians.** Care is required in distinguishing the rights of junior physicians to buy into an ASC. Some of the factors that need review are the number of shares, the justification for lower valuations, and the ability to obtain loans. A major requirement is that the transactions be at fair market value. If a lower value is used for a junior doctor than a senior one, that lower valuation should be justified.
- **Buy outs of doctors who fail to use the center.** Generally, since the investments are not tied into the quality and quantity of referrals, neither the medical practice nor the ASC should be able to terminate a doctor's right to perform surgeries at the ASC.
- **Purchases of additional shares in the ASC.** In the same way that doctors who underperform cannot be terminated, medical relationships can be hard to qualify for a safe harbor or a Stark Law exception when a doctor who uses the ASC a lot wants to buy additional shares in the surgery center. It may be feasible, depending on the circumstances which the doctors should review with experienced counsel, to buy shares from other physicians – provided the reason for selling the shares does not relate to the volume of the referrals and the sales are at fair market value.
- **The use of ancillary services such as anesthesia and pathology.** There are safe harbors and Stark Law exceptions for ancillary services. There are a variety of legal and medical issues that must be addressed for both anesthesia and for pathology which need to be reviewed with experienced healthcare lawyers.
- **Per-click relationships.** According to Becker's ASC review:

- *“There have traditionally been several different types of “per-click” arrangements for such items as gamma knives, lithotripters, lasers, CT and MRI scanners and other types of equipment. However, the government has now outlawed most per-click relationships (at least in the Stark context). Although the changes to the Stark Act and the accompanying regulations do not necessarily apply to surgery centers, the analysis and concerns are applicable under the Anti-Kickback Statute to surgery centers.”* CMS has provided some guidance on this issue as well – which generally prohibits the use of per-click payment arrangements.
- **Medical directorships.** The critical factor is that medical directorships are generally permissible – only if the physician is providing a valuable medical service and only if the payment for those services is based on fair market value. Generally, ASCs have at most a physician medical director and an anesthesiologist medical director. If there are medical directorships for each specialty, that raises a red flag.

HIPAA compliance

The ASC centers and the physicians often trade electronic medical health records. The exchange of the records must comply with HIPAA requirements. Often, a key danger when electronic records are being shared is that there is data breach of confidential information which requires that the patient be notified. A skilled healthcare lawyer can review the HIPAA compliance requirements and the protocols to help address breaches. Additionally, HIPAA now requires that patients have the *“right to receive medical records with little cost even if the surgery center must incur costs to provide the medical records.”*

GOT HIPAA? GET HIPAA? JOYCE EXPLAINS WHY AND HOW

Interview with an expert in healthcare privacy and security, both on the federal side with HIPAA, and the state side, especially California law.

Medical bylaws

The bylaws generally cover what the bylaws are, if and how the bylaws can be waived or changed, how a doctor can be removed from the medical staff, and how *“removal from the medical staff under the bylaws impacts redemptions from the surgery center as an owner.”*

The use of out-of-network reimbursement

Generally, the

“ability to profit substantially from out-of-network patients continues to decrease. While many parties profit from out-of-network payments, payors are increasingly aggressive regarding recoupment, collection of appropriate co-payments from patients and increasing co-payment and deductible responsibilities. Thus, the ability to make outsized profits or have serious negotiation leverage through the use of out-of-network continues to be hampered.”

Physician-owned equipment companies

“One of the interesting new scenarios is where physicians own an equipment company and sell equipment to the surgery center. In essence, the physicians become a middleman between the surgery center and the equipment provider. This allows the physicians to profit on the sale of equipment used in any cases that the physicians perform. ASCs should be cautious regarding these relationships.”

Additional ASC legal issues

Doctors who operate in ASCs and the ASCs must also be prepared to address any issues if the doctor advises patients through the use of telemedicine. All medical staff members must be properly licensed and certified. Only qualified medical personnel are allowed to perform medical procedures. Violations may result in charges of the unauthorized practice of medicine and state and local medical society complaints.

Additional issues include:

- Medicare and Medicaid coding and payment compliance issues
- Contracts between the doctors and the ASCs
- Corporate governance requirements
- Other applicable healthcare laws
- The purchase and sale of the membership interests and the purchases and sale of the ASC
- Overall compliance plans

While ambulatory surgery centers are becoming the norm for the fairly routine surgery, there are dangers that the relationship between the ASC and the doctors who use the ASC may violate the AKS and Stark Law. Skilled healthcare lawyers can explain when ASC safe harbors and Stark Law exceptions may apply.

Contact Cohen Healthcare Law Group, PC for legal counsel on healthcare transactions, regulatory compliance, and FDA and FTC law. Our experienced healthcare & FDA attorneys advise healthcare companies and healthcare providers ranging from medical centers, to integrative and functional medicine practices, cosmetics and supplement companies, and medical device manufacturers.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.