

Do You Know the Key Differences Between the 4 Ambulatory Safe-Harbors to the Federal Anti-Kickback Statute (AKS)?

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The Anti-Kickback Statute (AKS) forbids physicians from knowingly and willfully soliciting, paying, offering, or accepting remuneration to:

- Refer a patient for services or any item for which the payment for that service or item is made (in whole or in part) by a Federal health care agency or
- Buying, ordering, leasing (or recommending buying, ordering, or leasing) any service, good, or facility (in whole or in part) for which payment for that service, good, or facility is made by a Federal healthcare program

The federal anti-kickback statute (AKS) is violated if the scheme is indirect or direct, cover or overt, and for cash or an in-kind return.

Medicare and Medicaid are the two prime examples of Federal health care programs that pays for services, goods, and facilities. Remuneration is fairly broad in scope and essentially includes anything of value.

The Anti-Kickback Statute is a federal law. Violators can be given a criminal record and a prison sentence. Fines can be substantial and the violator will need to return any improperly received payments – reimburse the federal health care program directly or through the Department of Justice. Physicians who violate the Anti-Kickback Statute may lose their right to practice medicine. Violators may also be precluded from working with Medicare, Medicaid, or any federal health care program.

Safe harbors to the anti-kickback statute

The Anti-Kickback Statute laws do create “safe harbors,” which are ways/conduct that won’t qualify as violations of the Anti-Kickback Statute. Experienced healthcare lawyers can explain what actions and relationships qualify for safe harbor protection.

Without safe harbors, many of the relationships physicians and nurses have with hospitals would violate the Anti-Kickback Statute. Many of the relationships medical device companies and pharmaceutical companies have with physicians could also violate the Anti-Kickback Statute.

See our Prior post:

5 KEY STARK AND ANTI-KICKBACK LEGAL RULES YOU’LL WANT TO KNOW

While federal Stark and anti-kickback laws, and state law equivalents (often known as “mini-Stark” and “fee-splitting prohibitions”) are very complex, there 5 key legal rules you’ll want to know. [...]

Medical practitioners should understand that there is no mandatory requirement to meet safe harbor. Many relationships between medical practitioners and medical companies may fail to meet the Anti-Kickback Statute’s prohibitions for other reasons.

Some of the safe harbors in the Anti-Kickback Statute include:

- Renting space arrangements
- The sale of a medical practice
- Equipment rentals
- Discounts
- Personal service contracts
- Managed service contracts
- Group purchase organizations
- Certain types of investments such as investments in publicly traded companies, “underserved areas,” and group practices where all the “active investors” are licensed medical professionals
- Incentives for rural practitioners
- Many other types of relationships and agreements

What is an ambulatory surgery center?

Ambulatory surgery centers (ASC) are modern health care facilities where patients can get same day surgical care – instead of having to stay overnight at a hospital. Many Ambulatory surgery centers are closer to where the physician practices, sometimes in the same building. Ambulatory surgery centers are generally more convenient for patients. Advocates for Ambulatory surgery centers claim the risk of infection is less than in a hospital setting. Some of the prime users of Ambulatory surgery centers include procedures for:

- Endoscopy
- Pain management
- Plastic surgery
- Eye surgeries
- Podiatry
- Otolaryngology
- Orthopedic surgery
- Dental surgery

The ambulatory surgery center safe harbor

One key statutory safe harbor is the safe harbor for ambulatory surgery centers.

Subsection r of the safe harbors to the Anti-Kickback Statute 42 CFR 1001.952 – Exceptions, provides as follows:

“(r)Ambulatory surgical centers. As used in section 1128B of the Act, “remuneration” does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the Ambulatory surgery centers, patients referred to the investment entity by an investor are fully informed of the investor’s investment interest, and all of the applicable standards are met within one of the following four categories

- *surgeon-owned Ambulatory surgery centers ;*

- *single specialty Ambulatory surgery centers ;*
- *multi-specialty Ambulatory surgery centers ; and*
- *hospital/physician-owned Ambulatory surgery centers*

Similarities among the four Ambulatory surgery centers safe harbor categories

There are key differences among the four different types of Ambulatory surgery center investments. The common threads among those four types are:

- The Ambulatory surgery center must be properly certified
- 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.
- As with many of the safe harbors, the investments can't depend on the value or the volume of any referrals
- Secondary (ancillary) services such as anesthesia care must be an integral part of the Ambulatory surgery center procedure in order to bill Medicare, Medicaid, or other federally funded health care programs. The ancillary services can't be separately billed to these federal health care plans. The official statutory language is that

“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.”

- The doctors and the Ambulatory surgery center can't violate any federal health care discrimination laws or regulations
- 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.

A common violation of the Anti-Kickback Statute that is not protected through an Ambulatory surgery center safe harbor is inducing another physician to perform in the Ambulatory surgery center by offering the outside physician referrals if they perform their procedures at the ambulatory surgery center.

The Ambulatory surgery center safe harbor income test

The Anti-Kickback Statute legislation wants to make sure that the doctor's investment in the Ambulatory surgery center is tied into their medical practice – and not as a means to profit from referrals. For this reason, the Ambulatory surgery center safe harbor for surgeon-owned practices and single specialty practices requires that:

“At least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures, “- at an ambulatory surgery center or hospital surgical facility.

This income test applies to surgeon owned and single-specialty Ambulatory surgery centers . The requirement also applies to multi-specialty Ambulatory surgery center investments (safe harbors) with the additional requirement that the 1/3 income be from just the investment Ambulatory surgery center.

The examination of the 1/3 income test does not apply to hospital/physician Ambulatory surgery centers. The trade-off is that there are other very strict requirements the hospital/physician Ambulatory surgery center safe harbor must meet. These extra requirements are:

“(v) The entity 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 set forth in paragraph (b) of this section; 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 set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.

(vii) 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 Ambulatory surgery center (unless such costs are required to be included by a Federal health care program).

(viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.”

Additional Ambulatory surgery center safe harbor considerations

The definition of an ambulatory surgery center does not include cardiac catheterization centers, facilities, for radiology oncology, and other specialized types of surgery centers. Only Ambulatory surgery centers certified by Medicare are included for safe harbor Ambulatory surgery center protection.

The procedures that Medicare is covering in Ambulatory surgery center centers are expanding. An experienced Ambulatory surgery center healthcare lawyer can explain which facilities and which procedures are eligible for the Anti-Kickback Statute safe harbor. The expansion of eligible procedures can help physician-owned and single-practice Ambulatory surgery center meet the one-third income test.

The Office of Inspector General is not currently requiring that the investors in the Ambulatory surgery center be 100% completely owned by physicians. Outside investors (who can't refer patients to the Ambulatory surgery center and can't perform procedures at the Ambulatory surgery center on patients they do refer) must meet some additional requirements:

- They can't be employed by the Ambulatory surgery center or can't be employed by an investor
- They generally can't be in a position to influence referrals or provide services/items to the ambulatory surgery center

Management service organizations cannot invest in the Ambulatory surgery center.

Many other factors (in the statutes, in the OIG rulings, and elsewhere) can also affect Ambulatory surgery center safe harbor status.

The four Ambulatory surgery center safe harbors defined

In addition to the similarities and differences among the four types of Ambulatory surgery center safe harbors, it is important to understand how each category is defined.

Standard Ambulatory surgery center safe harbor for surgeon-owned Ambulatory surgery centers

The law for surgery-owned Ambulatory surgery center is as follows. The three other categories have similar provisions. Some of the key differences have been noted. Your Ambulatory surgery center investment healthcare lawyer can explain any other key differences.

(1) Surgeon-owned Ambulatory surgery centers – All of the investors are general surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the entity and perform surgery on such referred patients; surgical group practices (as defined in this paragraph) composed exclusively of such surgeons;

(2) Single-Specialty Ambulatory surgery centers – All of the investors are physicians engaged in the same medical practice

specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices (as defined in this paragraph) composed exclusively of such physicians;

(3) Multi-Specialty Ambulatory surgery centers – All of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices, as defined in this paragraph, composed exclusively of such physicians”

(4) Hospital/Physician Ambulatory surgery centers – At least one investor is a hospital, and all of the remaining investors are physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section; group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph)

All four categories also include the following definition – “investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors.”

Experienced health care lawyers understand how important relationships are between physicians and other entities such as hospitals, laboratories, and other medical providers or medical companies. Meeting with a skilled Anti-Kickback Statute attorney can help the physician understand what relationships may violate federal law. The lawyer can then explain what safe harbors such as ambulatory-surgery-center safe harbors may protect the physician’s investments. The attorney will also explain the differences among the four different types of Ambulatory surgery center safe harbors: surgeon-owned Ambulatory surgery centers, single specialty Ambulatory surgery centers, multi-specialty Ambulatory surgery centers, and hospital/physician-owned Ambulatory surgery centers

Speak with an experienced health care lawyer before you plan any investments in an ambulatory service center. The difference between investing correctly or incorrectly can be the difference between your freedom and a criminal sentence which may include jail time and can mean saving money versus having to pay substantial fines, costs, and other damages.

Contact Cohen Healthcare Law Group, PC. today. We have the experience and resources to help you create an ambulatory surgery center which can better comply with Ambulatory surgery centers safe harbors.

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