

# BECKER'S ASC REVIEW

## BUSINESS AND LEGAL UPDATE

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### **THE OFFICE OF INSPECTOR GENERAL APPROVES OF A HOSPITAL PHYSICIAN SURGERY CENTER JOINT VENTURE**

The Office of Inspector General ("OIG") recently issued an OIG Advisory Opinion relative to hospital physician joint ventures. There, the OIG approved the purchase by a hospital of an ownership interest in a gastrointestinal surgical center. The core concept set forth in the Advisory Opinion related to steps to be taken by the Hospital to assure that it was not inducing or requiring its employees or related physicians to use or refer to physicians that use the surgical center. Specifically, the Hospital would be prohibited from compensating its own physicians based on the referrals to the surgical center or surgeons that use the center, or requiring any of its physicians to refer to or use the surgical center.

As a separate matter, it should be noted that the transaction included, on a fixed annual fee basis, the physician group managing the center.

For a copy of the Advisory Opinion, please call Scott Becker at (312) 750-6016 or Email at [scott.becker@rosshardies.com](mailto:scott.becker@rosshardies.com).

### **SURGICAL AND SPECIALTY HOSPITALS: A LEGAL PRIMER**

This article provides an overview of fourteen legal issues that impact the development of surgical and specialty hospitals.

#### **I. The Stark Act**

The Stark Act prohibits referrals to entities with which the referring physician has a financial relationship for certain designated health services that may be reimbursable under a federal health care program, unless an exception applies. One such exception permits physicians to refer to specialty or surgical hospitals in which the physician has an ownership interest. This exception includes a requirement that the referring physician be authorized to perform services at the specialty or surgical hospital. Specifically, the hospital ownership exception provides as follows:

(3) Hospital Ownership. In the case of designated health services provided by a hospital (other than a hospital [in Puerto Rico]) if --

(A) the referring physician is authorized to perform services at the hospital, and

(B) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).

There are three principal observations to be made regarding the Stark Act and this exception. First, the requirement that the referring physician must be authorized to perform services at the hospital raises legal concerns, because many physicians may be authorized to perform services but may not ever actually provide services at the surgical hospital. In other words, a hospital might grant privileges to a physician for the sole purpose of qualifying for the Stark Act exception. While this may permit compliance with the Stark Act, it could potentially be viewed as an illegal sham or scheme under the Stark Act. Moreover, it simultaneously may give rise to a violation of the Anti-Kickback Statute on the basis that it constitutes remuneration in exchange for referrals. In its guidance relating to the Anti-Kickback Statute, the government has specifically expressed its concern with parties who make investments from which they can earn returns from indirect referrals. To avoid liability under the Anti-Kickback Statute, hospitals should ensure that its medical staff membership policies provide that hospital privileges should only be granted to physicians who are actually likely to use the hospital in some fashion. For example, a primary care physician who is privileged at a surgical hospital and refers patients there, but lives 100 miles from the hospital, may technically be "authorized to perform services" at the hospital as required by the Stark Act. However, this may raise legal issues in that the primary care physician, as a practical matter, may never be in a position to actually provide services at the hospital, and thus the granting of his privileges may be viewed as a sham, for the sole purpose of qualifying for the Stark Act exception.

Second, legislation has recently been introduced in the House of

Representatives that would substantially tighten the Stark Act exception for hospital ownership. This legislation would permit ownership by referring physicians only if "the ownership or investment interest is purchased on terms generally available to the public at the time." The term "generally available to the public" is used in other statutes to mean that shares must actually be publicly offered and traded pursuant to the federal securities laws. Alternatively, this may mean that surgical hospitals simply need to provide the same terms to physician and non-physician investors, and must allow non-physicians to invest in the surgical hospital. At this point, it is not clear that the bill will make it out of committee. In addition, the Ways and Means Committee of the House of Representatives has recently requested the General Accounting Office to review a series of issues relative to surgical hospitals, which may set the stage for further legislation under the Stark Act. Specifically, the Committee made, in part, the following request of the GAO:

Specialty hospitals, generally for-profit enterprises that specialize in high-volume, big-ticket, inpatient procedures, such as heart and orthopedic surgery, are a rapidly growing market trend in the United States. It is not clear how these hospitals fit into the care delivery framework and whether they raise health care costs or lower health care costs. Considering the possible ramifications of free-standing specialty or "boutique" hospitals, we request that the GAO examine these existing boutique hospitals and determine:

- Whether the presence of specialty hospitals increases utilization in a market area? For instance, if hospitals vigorously compete for patients through advertising, this raises the awareness of the services and often the utilization of a service. Has this led to increased health care costs to both consumers and the federal government?

- If specialty facilities exacerbate the growing nurse shortage and could lead to the

closure of surgical suites or other units in the full-service hospital?

- If ownership in specialty hospitals create incentives for physicians to under- or over-utilize services based on financial rewards, refer patients to their own facilities more than to competing hospitals or facilities where they do not have a financial interest, or provide services of a marginal clinical value to patients?

- If specialty hospitals provide better, more cost-efficient care than the hospitals they have replaced or with which they compete? Is there an improvement in care due to specialization and a higher volume of services? What would happen to a heart patient should his or her lungs fail in a boutique hospital? Can they provide full service treatment if necessary?

The GAO report in response to this inquiry is expected to be conducted this coming year.

Third, the Stark Act permits physician investment in the whole hospital itself, not investments in individual departments or subdivisions of a hospital. Here, concern also exists that the government may look negatively upon situations where the surgical hospital seems more akin to a surgery center or imaging facility. For example, many of the surgical and specialty hospitals being built today are much smaller than traditional hospitals, possibly having no more than four to eight beds, imaging capacity, and two or three operating rooms. Such hospitals often do not have the full set of emergency department resources of the typical acute care hospital.

## **II. Medicare/Medicaid Fraud and Abuse and Anti-kickback Law**

The Anti-Kickback Statute prohibits the offer, provision, solicitation or receipt of any sort of remuneration in exchange for the referral of any service potentially reimbursable under Medicare, Medicaid, or other federal health program. The following issues concern surgical and specialty hospitals with respect to the Anti-Kickback Statute.

There is no safe harbor that provides comfort for the development of surgical hospitals. Although there exists a safe harbor for certain small investment interests, the safe harbor requires that investing physicians not own more than 40% of the hospital, nor generate more than 40% of the volume of the hospital's business. Thus, it will be inapplicable to most surgical and specialty hospitals. As no safe harbor protection exists for such investments, it is extremely important

that the offering of shares in the development of the hospitals be done under carefully constructed prophylactic rules that help to demonstrate that the investors are not given special terms or remuneration in exchange for referrals. These rules might include:

1. All investors will have equal opportunity to purchase shares;
2. All investors will pay the same amount per share;
3. No investor will receive financing from another investor for the purchase of shares;
4. All returns will be based on ownership of shares;
5. All investors will be required to disclose to patients their ownership in the hospital;
6. No physicians shall be expected to make any level of indirect referrals to the hospital;
7. The hospital will not discriminate against Medicare or Medicaid or governmental health care program business;
8. Services of the entity will be marketed or furnished to all persons in a manner that is the same. (i.e., marketing of services will not be different based on who is an owner of the facility);
9. The targeted ownership group should not be differentiated or based on the volume or value of referrals;
10. The center will not track or distribute referrals from investor owners;
11. The real estate lease for the hospital will be consistent with fair market value for the space leased; and
12. A limited total number of investors will be permitted to invest per Regulation D restrictions.

Finally, the Office of Inspector General ("OIG") has expressed concerns in other contexts which should be carefully considered in this context. First, the OIG has negatively commented on arrangements which provide for the ability to derive profits from the provision of indirect referrals. Specifically, in Advisory Opinion 98-12, the OIG outlined its concerns with respect to ambulatory surgery centers as follows:

[T]his Office is concerned about the potential for investments in ambulatory surgical centers to serve as vehicles to reward referring physicians indirectly. For example, a primary care physician, who performs little or no services

in an ambulatory surgical center in which he has an ownership interest, may refer to surgeons utilizing the ambulatory surgical center, thereby receiving indirect remuneration for the referral through the ambulatory surgical center's profit distribution. Similarly, an investment by orthopedic surgeons in an ambulatory surgical center that is not equipped for orthopedic surgical procedures, or that is exclusively used by anesthesiologists performing pain management procedures on patients referred by the orthopedic surgeons, would be suspect.

As there is no specific safe harbor for surgical hospitals which invokes the extension of practice concept that exists in the ambulatory surgery center safe harbor, many parties have viewed surgical hospitals as providing an opportunity for the involvement of primary care physicians as owners in surgical hospitals. Here, we believe the OIG may also not approve of arrangements in which physicians who are indirect referral sources are brought in as owners.

## **III. State Self Referral and Anti-Kickback Laws**

Many states have enacted self referral and anti-kickback laws that mirror the federal Anti-Kickback Statute and the Stark Act. In fact, in certain states, there exist prohibitions that are applicable to ownership in surgical hospitals that are not applicable to surgery centers. For example, under Nevada law, physicians generally may not own interests in hospitals. However, it is permissible under Nevada law for physicians to own interests in surgery centers. Moreover, Michigan, Illinois and other states have laws that limit the ability of a physician to invest in and derive profits from referrals to entities if the investing physician does not directly perform services at such entity.

## **IV. Certificate of Need**

Approximately thirty states restrict the development of surgical and specialty hospitals through Certificate of Need or Determination of Need laws. Further, certain other states such as Minnesota have implemented direct moratoriums on the development of new hospitals, and other states such as Wisconsin have limited the total number of beds that can be built. In many states, it is nearly impossible to obtain a Certificate of Need for new hospital projects at this time. In such situations, planning efforts may involve utilizing a local Certificate of Need expert in applying for a

Certificate of Need or, alternatively, working with state health care associations in an effort to lobby for the repeal or expiration of the Certificate of Need law.

#### V. Licensure

Many states do not categorize surgical or specialty hospitals separately from other types of hospitals. Thus, surgical and specialty hospitals in most states must be licensed under the general hospital licensing statute. Hospital licensure statutes have various requirements which may affect small specialty or surgical hospitals, including provisions which mandate a minimum size of operating room, or which require certain types of emergency services. In many states, a hospital may operate with a very small-scale emergency department, as opposed to the typical full-scale, full-service emergency room. For instance, it may be permissible for a specialty or surgical hospital to staff a 24-hour urgent care center. As the development of surgical and specialty hospitals gains momentum, we expect that state hospital associations will lobby relatively aggressively for state laws which require surgical and specialty hospitals to meet the more full-scale emergency requirements or other requirements which are applicable to tertiary care and other hospitals.

#### VI. Fair Share Laws

Indicative of the sort of actions state legislatures may take in response to the development of surgical and specialty hospitals, the State of Oklahoma has recently adopted a "fair share" law. Under the Fair Share Law, all new providers must provide at least one-third of its services to Medicare, Medicaid or indigent patients. Specifically, the Oklahoma Fair Share law requires that "at least thirty percent (30%) of its annual gross revenues are from Medicare, Medicaid, uncompensated care, and/or corporate tax contributions." Facilities which do not reach the 30% threshold are required to pay an assessment equal to the difference, up to 30% of the facility's total gross revenue. Fees collected "shall be deposited into an uncompensated care fund. Disbursement from the fund shall be made to facilities that exceed the thirty percent (30%) threshold." This law is intended to prevent surgical hospitals from "cherry-picking" higher paying patients from tertiary hospitals and other providers.

#### VII. Antitrust

The development of a surgical or specialty hospital can raise a variety of antitrust issues. First, in many situations, the specialty or surgical hospital may desire to resort to the use of the antitrust laws as hospitals work with payors to exclude specialty hospitals from managed care

panels. Second, the specialty hospital or surgical hospital must itself be careful that it is not developed with another party such that two parties together are viewed as being a combination which provides a monopoly in the provision of certain types of services. Third, the surgical hospital's participants must be careful to avoid any appearance of the intent to conspire to fix prices, collectively negotiate, or conduct a group boycott.

#### VIII. Tax Exempt Issues

Many of today's specialty and surgical hospitals are being developed in partnership with tax exempt hospitals. In such situations, the participating tax exempt hospital has two principal concerns: first, whether the project will cause it to lose its own tax exempt status, and second, whether it may treat the income derived from the surgical hospital as exempt income. Here, the organizational and operational documents which govern the joint venture must provide the exempt entity with the authority to assure that the venture will further community needs, and the tax-exempt entity must actually exercise that power. The requirement that a joint venture involving a tax-exempt partner must be principally intended to benefit the exempt partner's charitable purposes was discussed in Revenue Rule 98-15, in which the IRS explained that

A: § 501(c)(3) organization may form and participate in a partnership, including an LLC treated as a partnership for federal income tax purposes, and meet the operational test if participation in the partnership furthers a charitable purpose, and the partnership arrangement permits the exempt organization to act exclusively in furtherance of its exempt purpose and only incidentally for the benefit of the for-profit partners. . . . However, if a private party is allowed to control or use the non-profit organization's activities or assets for the benefit of the private party, and the benefit is not incidental to the accomplishment of exempt purposes, the organization will fail to be organized and operated exclusively for exempt purposes.

It is unclear how Revenue Ruling 98-15 will be interpreted to apply to whole-hospital joint ventures, which are ventures between a tax-exempt hospital and a for-profit entity, and the entire hospital is taken over by the joint venture entity (as opposed to the more familiar situation where one or more of the hospital's ancillary services, such as outpatient surgery services, are turned over to the joint venture entity). Currently, a case is pending in Texas which may clarify how Revenue Ruling 98-15 applies to whole-hospital joint ventures.

#### IX. Affiliated Service Group Issues

Physician groups which participate in the development of surgical or specialty hospitals must take care to ensure that the hospital is not deemed an "affiliated service group" with the group practice. For practical purposes, affiliated service group restrictions make it more difficult for the group practice to meet certain anti-discrimination and employee tests with respect to its own self-employment and profit sharing plan.

#### X. Funding Specialty Hospital Contributions Through Pension Dollars

Use of pension plan dollars to invest in a surgical hospital can generate unrelated business income for the pension plan, resulting in an increased income tax liability. This means that income derived by the surgical hospital that is passed on to the shareholder is actually taxed to the plan on a yearly basis, as opposed to being deferred until withdrawn. Further, pension laws must be carefully reviewed to ensure that the investment is not deemed an improper or restricted investment in an affiliated party.

#### XI. Medicare Certification

It is often a much longer process to obtain Medicare certification for a surgical hospital than for a surgery center. Thus, the developer of a surgical hospital must make the effort to examine early the expected timing for receiving Medicare certification and, further, must make provision for working capital to assure that it can fund operations before Medicare certification is obtained.

#### XII. Securities Laws

The offering of shares in a surgical hospital is more likely to be deemed the offering of securities than the offering of shares in a surgery center.

The term "security" means any note, stock, treasury stock, bond, debenture, evidence of indebtedness, certificate of interest or participation in any profit-sharing agreement, collateral-trust certificate, preorganization certificate or subscription, transferable share, investment contract... or any interest or instrument commonly known as a "security".

The Supreme Court has enunciated that in general, an investor invests in a "security" where he "invests his money in a common enterprise and is led to expect profits solely from the efforts of the promoter or a third party . . . ." In other words, whether an investment in a particular venture will be deemed a "security" largely

depends on whether and to the extent that each investor's own efforts, rather than the efforts of others, will affect the success or failure of the venture. Surgical centers generally have fewer investors than surgical and specialty hospital developments. Moreover, as opposed to investors in surgical hospitals, investors in surgery centers are more likely to be actively involved in the operations of the center, and thus more likely to have the surgery center deemed to be an extension of their practice. As surgical and specialty hospitals are more likely to have a greater number of investors, each individual investor will be proportionally less actively involved in the hospital's operations.

As the offering of interests in a surgical or specialty hospital is more likely to constitute the offering of a security, the offering must comply with the state securities laws (Blue Sky laws) and federal securities laws. Fortunately, many securities laws are less restrictive of developments where all of the investors are "accredited," meaning that the investor has a high income and therefore requires less protection under the securities laws. However, as many surgical hospitals include investors who are not surgical specialists, it is more often the case that offerings will include non-accredited investors. The involvement of non-accredited investors typically serves to raise the level of disclosure that must be made to potential investors.

### **XIII. False Claims Act**

As several payment systems may apply to surgical and specialty hospitals, such as inpatient and outpatient prospective payment systems, billing for services is more complex for surgical and specialty hospitals than for ambulatory surgery centers. Further, many surgical hospitals are developed with less administrative staff than larger hospitals. Thus, there is heightened concern in the billing and claims context that the hospital regularly conduct billing and claims audits. There is extensive liability associated with submitting improper or incorrect claims, whether due to negligence, recklessness or simple error.

### **XIV. Utilization Review**

Various federal statutes and regulations, as well as a number of judicial decisions, suggest that physicians who own an interest in a particular health care entity should not participate in utilization review activities for the entity. Thus, it may be necessary for a physician-owned surgical or specialty hospital to outsource its utilization review activities.

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We expect there will be significant development of surgical hospitals over the

next two to five years. Currently, there are approximately one hundred physician-owned hospitals in the United States -- this number is likely to more than double within the next few years.

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