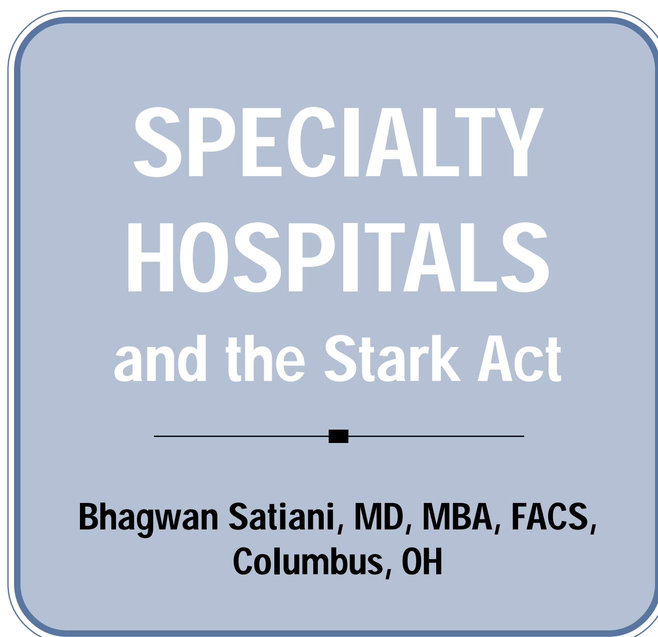
The number of specialty, or "boutique," hospitals has proliferated in recent years. As more of these centers open, concerns about how these facilities might be affected by the "Stark Act" and related legislation have emerged. This article summarizes the purposes of these laws and considers how they might influence boutique care.



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Background

The Ethics in Patient Referrals Act (EPRA) is commonly referred to as the Stark Act in reference to the legislation's author, Rep. Fortney H. "Pete" Stark (D-CA). The law was enacted in 1989 after studies purported to show that medical services were being excessively used if the physician requesting them had a financial interest in the entity delivering that item/service. Amendments to the EPRA became informally known as "Stark I," which prohibits referrals to entities in which a physician or a family member has a financial relationship for certain health-related services that may be reimbursed by a federal program.[1,2] A case in point would be if a physician referred a patient for laboratory testing to a facility in which he/she or a family member had ownership interest. Another violation would be if the physician received an incentive bonus that was tied to the volume of patients that were referred to the laboratory.

There are major differences between the previously enacted Anti-Kickback Statute (AKBS) and the Stark Act. The AKBS applies to any business, whereas the Stark Act applies expressly to physicians. Another difference is that the AKBS places the burden of proof on the government to prove that the physician "knowingly and willfully" committed a violation, whereas no such proof of intent is required under the Stark Act. In essence, under the Stark Act it is immaterial whether the defendant acted in good faith or was unaware of the law.

As passed, the Stark Act was complicated, largely ambiguous, and interfered with day-to-day physician-patient interactions. To better define the scope of the law, it was expanded under the Omnibus Budget Reconciliation Act of 1993 to Medicaid patients and additional "designated health services." The additional services in "Stark II" included: physical therapy, occupational therapy, radiology, radiation therapy, durable medical equipment and supplies, parental and enteral nutrients, prosthetics, orthotics, and prosthetic devices and supplies, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.

Congress also identified several exceptions where legitimate services and financial relationships were exempt from the law, which include: referrals for services provided by other surgeons within the same group practice; certain in-office ancillary services; referrals within health maintenance organizations; one-time sale of a practice or property by a physician; and referrals to a hospital where the physician has privileges to perform services and he or she holds an ownership or investment interest.

The exception that allows a physician to refer patients to a hospital in which he or she has ownership interests comes with some caveats.[3] The first stipulation is that the physician must have privileges to perform services at the hospital and the ownership (or investment) must be in the hos-

pital itself and not in a department or subdivision of the hospital. This limitation may be easily addressed by granting the investor physician staff privileges. However, if the physician then does not provide services at the hospital, regulators may either consider the act of granting privileges a façade, or they may invoke the AKBS by arguing that referrals were being made in exchange for compensation. Investing physicians owning more than 40 percent of the specialty hospital or generating more than 40 percent of the volume will not be protected by current safe harbor laws and expert legal advice is necessary to deal with the AKBS. The second exemption regarding the investment not being in a department/subdivision but the entire hospital was designed to dilute the economic effect of any physician referrals/activity.

The hospital lobby is attempting to strengthen this second loophole in order to curtail the growth of specialty hospitals. In 2001, a total of 133 heart and 82 cancer centers were built, and another 300 facilities entered the construction/design phase.[4] Rep. Jerry Kleczka (D-WI) and Representative Stark introduced The Hospital Investment Act of 2001, which aims to close the loophole in the current conflict of interest laws exempting physician self-referrals to hospitals in which they have ownership interests. Under the legislation, physicians could refer patients to hospitals in which they have ownership interests, but only if the interests were purchased on terms also available to the general public at the time. This may imply that shares in this investment be publicly traded under current securities regulations and be offered to nonphysician investors as well. The House Ways and Means Committee has asked the General Accounting Office (GAO) to investigate the entire specialty hospital issue. Following are some of the questions that the committee raised:

- Do specialty hospitals raise or lower health care costs?
- What will be the financial impact of specialty hospitals on full-service hospitals?
- Is there likely to be increased use in areas served by these hospitals?
- Will these hospitals negatively affect the nursing shortage?
- Will ownership by physicians in specialty hospitals create perverse incentives to overuse services? Does the current exception to the Stark Act of allowing physicians to invest in the entire hospital still make sense for specialty hospitals?
- Is health care in the community served by these hospitals improved due to super-specialization and increased efficiency? Are there provisions to arrange for transfer of patients to full-service hospitals if needed?

Boutique hospitals

Not-for-profit (NFP) hospitals have already taken steps to attract well-paying customers and give current ones more value for their money by taking advantage of their brand name. These offerings include luxury suites, catered meals, private nursing, and specialty centers within the hospital. Another niche service is "premium" outpatient service of the sort offered by the Dana Center at the NFP Virginia Mason Hospital in Seattle, WA. The Dana Center offers individual subscribers round-the-clock access to internists by cell phone or e-mail, as well as house and office calls by physicians who spend more time with subscribers for a $3,000 annual fee.

Numerous hospitals have constructed "centers of excellence" within their NFP structure to cater to patients with cardiac, vascular, neurological, orthopaedic, and other illnesses as joint ventures with their medical staffs. It is only when physicians elect to provide the same service outside the hospital-physician joint venture framework that objections are voiced.

The American Hospital Association (AHA) and NFP hospital groups have raised several concerns regarding the growth of boutique centers. They are as follows:[3]

1. Investor physicians would "cherry pick" the most paying patients and treat the rest at the NFP facilities. The AHA is concerned about the willingness of the for-profits (FPs) to care for the indigent. Under current law, all hospitals that receive Medicare and Medicaid funding are required to participate in a program that equalizes the impact of indigent care. Many states have "fair share" laws that require all new providers to offer up to one-third of their services to Medicare, Medicaid, or indigent patients, or else compensate the state for the difference. Lewin Group, a consulting firm, compared patient illness severity, in-hospital mortality, length of stay, and discharge patterns among eight MedCath heart hospitals and 1,139 commu-

nity and teaching hospitals that perform open-heart surgery.[5] MedCath patients had a higher case-mix severity, a 12.1 percent lower mortality compared to Medicare cardiac patients in other hospitals, a 17.4 percent shorter length of stay, and a greater proportion of patients discharged to their home compared to area hospitals.

2. Community hospitals already are stretched to their limits in terms of low reimbursements, staffing shortages, and high operational costs. However, the average hospital operating margin has increased from 2.45 percent in 1999 to 4.27 percent in 2001, and profitability has stabilized at 4.2 percent in 2001.[6] The hospital lobby points to studies that show that Medicare costs have risen faster in communities with only for-profit hospitals[7] and that the latter have higher administrative and nonpersonnel costs than NFP hospitals.[8]

3. Specialty hospitals deprive NFP hospitals of the profit that the latter use to subsidize less-profitable areas such as burns, trauma, and transplant care.

NFP hospitals argue that their efforts to tie hospital privileges to lack of ownership interest in specialty hospitals is not intended to be an "economic credentialing" issue, but more of a conflict of interest issue. The hospital boards have revoked privileges for medical staff members who invest in these specialty hospitals.[9] One health system estimates it would lose $28 million to a specialty orthopaedic hospital planned by physician investors—money that is being used to subsidize almost $85 million in uncompensated charity care.[9] However, an AHA survey of 4,908 facilities in 2001 showed that hospital spending on uncompensated care has fallen to its lowest level in two decades to 5.6 percent of their total expenses.[10] Case law clearly gives hospital boards the broad authority to protect the hospital's interests.[11,12] Legal precedent notwithstanding, Burda urges the not-for-profit hospitals to compete against specialty centers and asks, "Why not embrace competition? Rather than acting like spoiled brats whose best friend went to play at someone else's house, why not offer the same service, albeit better and cheaper?"[13]

The physicians contend that these specialty hospitals will create competition and thereby reduce costs and improve patient services. They also point to the fact that in contrast to NFPs, the FP centers will pay their fair share of income, real estate, sales, and property tax, which will benefit the community. They object to the use of economic credentialing and claim it is not in the public interest.

Penalties under the Stark Act

Penalties under the Stark Act include: civil penalties of up to $15,000 for each illegal referral, exclusion from Medicare/Medicaid, denial of payment for services, refunding of payments already made, a fine of up to $100,000 for each arrangement that involves an illegal cross-referral agreement, and civil penalties of up to $10,000 per day for organizations that fail to report details of any violations. To avoid the perception of impropriety, specialty hospitals should grant medical staff privileges to physicians who are likely to provide services at the hospital in some fashion. A surgical hospital may have to be careful in having a primary care physician as an investor who may not be in a position to provide any legitimate services at the facility. [1,2]

Conclusions

NFP hospitals are faced with an increasingly competitive environment, potential loss of market share in the most lucrative specialties (cardiac and orthopaedic care), and static reimbursement from health care payors. While they wait for long-term help from the state legislatures and Congress to possibly strengthen the Stark Act, they are using short-term measures, such as economic criteria, to discourage physician investment in specialty cen-

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ters. NFP hospitals have a choice to make. They can look upon their medical staffs as equal partners with regard to specialty hospitals or let market forces determine which emerging models will succeed and create better value for consumers.

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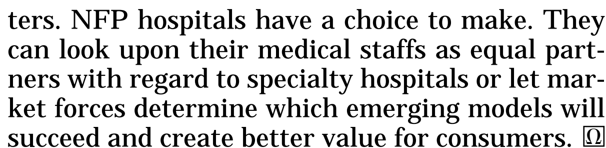

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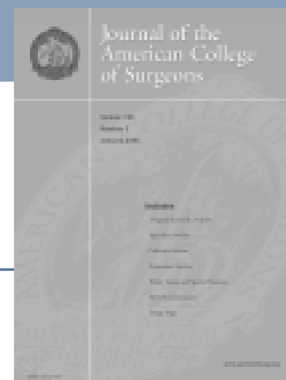

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