TAKING HEALTHCARE'S PULSE: LEGAL ISSUES INVOLVED IN HEALTHCARE BUSINESS TRANSACTIONS

RENEE A. PISTONE

I. Introduction 89
A. The Purpose and Role of a Physician Hospital Organization 90
B. Formation of the Physician Hospital Organization 90
C. Facts 91
D. Determination of Physician Membership in the Joint Ambulatory Surgical Center 92
E. Internal Structure of the Joint Ambulatory Surgery Center 92
1. Purpose: Compliance with Safe Harbor 92
2. Functions of the Joint Ambulatory Surgical Center Physician Shareholders 93
II. The Legal Ramifications of this Transaction 94
A. Factors in Regulatory Compliance: 94
B. Southern Methodist Hospital's Governance Over Referrals 94
C. Physician Compensation 95
III. Analysis of the Legal Implications 95
A. Remuneration: The Anti-kickback Statute, Violations, & Fines 95
B. Safe Harbor Regulations 95
C. Professional Ethics 97
IV. Conclusion and Recommendations 97

I. INTRODUCTION

There are many federal regulations to consider when a healthcare lawyer creates and evaluates a particular healthcare business transaction.[1] The healthcare market is highly competitive with the formation of healthcare business transactions on the rise.[2] Hospitals and physicians seek dynamic and cost effective ways to

---

[1] Natalie Marjanik, *Risky Business: Proposed Reform of the Antitrust Law As Applied to Healthcare Provider Networks,* 24 AM. J.L. AND MED. 59 (1998).

[2] *See generally*, James Blumstein, *The Fraud & Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. AND MED. 205 (1996). The latest trend is that more physicians are forming organizations out of necessity to stay competitive in the healthcare market, *see generally,* Thomas Bodenheimer, et al., *Can Money Buy Quality? Physician Response to Pay for Performance,* 3 IND. HEALTH L. REV. 443 (2006). For a discussion about new roles for physicians, *see*, Barry Silbaugh, *Up-and-Comer: Physician-Executives Take the Lead,* MODERN PHYSICIAN, May 1, 2006 at 9. For more about the impact of changes in the healthcare market, *see generally,* Jay Greene, *Where is It All Going? Physician Group Owners and Operators Face Bigger Financial Squeeze in 2006*, MODERN PHYSICIAN, January 1, 2006 at 1.

deliver healthcare[3] and partnerships are being formed between physicians and hospitals. These partnerships add to the marked increase in healthcare business transactions along with the progressed development of the physician hospital organization ("PHO").[4] Attorneys who execute healthcare business transactions on behalf of clients have to follow the federal laws. Part I sets forth potential ethics pitfalls within a hypothetical healthcare business transaction. Part II analyzes legal implications that arise from these transactions. Part III considers and surveys the ethical issues that physicians face in such transactions. Part IV sets forth the conclusions and recommendations.

A. The Purpose and Role of a Physician Hospital Organization

The main purpose of a PHO is to function as a separate legal entity. It allows for a hospital and physicians to enter into contracts jointly with managed care entities, insurance companies, and payers in general. A physician participant may be a sole practitioner or he or she may be a part of a physician's organization that already has a relationship with the hospital.[5]

The rationale here is that when a PHO is properly organized, capitalized, governed, and administered it can be a useful tool to overcome internal conflicts among physicians and between hospitals and physicians. Clearly, it must be founded on mutual trust and cooperation to accomplish its goals. A PHO can also serve as an important transitional form during the continued changes payers are implementing. Due to the steadily increasing healthcare costs, payers are moving away from fee for service compensation, and increasing their capitation agreements.[6]

B. Formation of the Physician Hospital Organization

The contract for the healthcare business transaction should state what type of entity is being created, for example: contractual joint venture, partnership, limited partnership, corporation- for-profit or non-profit, or the limited liability company.[7] The limited liability company is easily started by filing Articles of Organization

---

[3] Eleanor Kinney, *Tapping & Resolving Consumer Concerns About Health Care*, 26 AM. J.L. AND MED. 335, (2000). *See also,* Jennifer Lubell, *Payment Protest: Docs Press Congress to Fix Formula and End Cuts,* MODERN HEALTHCARE, July 9, 2007; *see* Jennifer Lubell, *Seeking a Proper Diagnosis: Pa. Company's Physician-Advisor Teams Examine Hospital's Business-Plan Problems*, MODERN HEALTHCARE, April 24, 2006 at 36.

[4] This article focuses on the physician hospital organization ("PHO"). A physician hospital organization ("PHO") is a form of joint venture between a group of physicians and a hospital to combine their resources to effectively deliver healthcare. *See, generally,* McDowell, *The State Action Doctrine & The Local Government Antitrust Act: The Restructured Public Hospital Model,* 14 AM. J.L. AND MED. 171 (1988). *See,* e.g. *Healthamerica Pa., Inc. v. Susquehanna Health Sys.,* 278 F. Supp. 2d 423 (2003) (formation of an integrated delivery system was in conformance with Clayton Act antitrust guidelines). For more on the effectiveness of an integrated delivery system, *see*, Thomas Greaney, *Managed Competition, Integrated Delivery Systems and Antitrust,* 79 CORNELL L. REV. 1507 (1994).

[5] Thomas M. Gorey, PHYSICIAN ORGANIZATIONS, *Cascade Physicians,* 55-62.

[6] *Id.*

[7] The hypothetical fact pattern deals with a physician hospital organization that is a limited liability company.

with the state and an Operating Agreement which illustrates that governance and operations is also developed.[8] The advantages of a limited liability company are that it combines the tax treatment of a partnership with the limited liability characteristics of a corporation.[9] There is greater flexibility with this entity in determining the rights and responsibilities of its members.[10] The hypothetical fact pattern below involves the creation of a PHO using the form of a limited liability company.

C. Facts

Southern Methodist Hospital is a non-profit, tax-exempt corporation that operates an acute care facility in Tennessee.[11] Southern Methodist Hospital has a number of affiliations with physicians, employees, independent contractors, and medical staff members. It operates facilities that provide orthopedic surgery and related services to Southern Methodist Hospital outpatients and non-hospital patients as they are referred to it. Currently, Southern Methodist Hospital seeks to initially acquire a 15% ownership or equity interest in an established single specialty orthopedic ambulatory surgical center called Joint Ambulatory Surgical Center of Tennessee. It will acquire this ownership interest in exchange for a capital contribution and a line of credit for the Joint Ambulatory Surgical Center.[12] Ultimately, Southern Methodist Hospital seeks to increase its share to 40% in exchange for an additional capital contribution. Southern Methodist Hospital certifies that all loans made to the Joint Ambulatory Surgery Center are made with a fair market value interest rate.[13]

The Joint Ambulatory Surgical Center of Tennessee is a limited liability company that operates a "free-standing" single-specialty orthopedic surgical center. It is indirectly owned by a physician group practice through a holding company.[14] None of the substantial capital contributed by the physician shareholders came from funds loaned or guaranteed by the Joint Ambulatory Surgical Center, Southern Methodist Hospital, any indirect investor, or entity acting on behalf of one of the aforementioned parties. This is an important detail

---

[8] Joseph Mantone, *Amerinet Changing Management, Bylaws* MODERN HEALTHCARE, July 24, 2006 at 33.

[9] *Id.*

[10] *Id*.

[11] Southern Methodist Hospital is part of a group of affiliated entities owned and controlled directly by The Southern Methodist Health Systems Corporations. The affiliated entities include a foundation, a managed care network, and several other hospitals and related health care entities. This hypothetical treats all of the foregoing as one single collective entity and calls it the Southern Methodist Hospital.

[12] Southern Methodist Hospital's interest is limited to 15% so that the surgery center can qualify for the physicians' office exemption under Tennessee's certificate of need law. The surgery center will receive a certificate of need that authorizes Southern Methodist Hospital to have a 40% equity interest and approve an upgrade of the Surgical Center's equipment.

[13] For a discussion of "fair market value" in arms length transactions, see, generally, Stephen R. Latham, *Regulation of Managed Care Incentive Payments to Physicians*, 22 AM. J.L. AND MED. 399 (1996).

[14] This hypothetical organization called the Joint Ambulatory Surgical Center is loosely based on the Baltimore Medical Group (BMG).

because it helps to avoid fraud and abuse. This particular structural component is required in order to be in conformance with federal laws.

D. Determination of Physician Membership in the Joint Ambulatory Surgical Center

(1) the relationship must be exclusive
(2) the physician must make an initial investment
(3) pay an annual participation fee

On the more practical side:

(1) the physician must be board certified
(2) have a good reputation amongst peers
(3) be willing to participate in managed care

E. Internal Structure of the Joint Ambulatory Surgery Center

1. Purpose: Compliance with Safe Harbor

Here, there is a group of sixteen physicians that own the center. It is a professional company that meets the requirements of a "group practice" under the safe harbor provision.[15] All sixteen physicians are shareholders and are orthopedic surgeons in the state of Tennessee.[16] Eight physician shareholders meet the one-third practice income test under the Ambulatory Surgical Center safe harbor.[17]

The safe harbor requires that each orthopedic surgeon investor's medical practice income (from all sources for the previous fiscal year) be derived from the orthopedic surgeon's performance of ambulatory surgical procedures under the regulations. The remaining physician shareholders derive more than one-third of their incomes (from all sources for the previous fiscal year) from the performance of procedures that meet the definition of ambulatory surgical procedures.[18] Each physician shareholder (except for one) is an active member of the medical staff at Southern Methodist Hospital.

---

[15] 42 C.F.R. §1001.952 (p)(3).

[16] The sixteen physician shareholders are: Dr. James Phillip Thorpe, Dr. Ellie Ann Smith, Dr. Vincent Michael Soy, Dr. Lynn Victor, Dr. Stephen Boss, Dr. Susan Mann, Dr. Kurt Kent, Dr. Anthony Lewis, Dr. Jean Simmons, Dr. Len Fitzpatrick, Dr. Arthur Isaacs, Dr. John Sharp, Dr. Matthew Shaw, Dr. Brian Bass, Dr. Keith Jones, and Dr. Ted Spelling.

[17] 42 C.F.R. §1001.952 (r)(1)(ii).

[18] 42 C.F.R. §1001.952(r)(5).

2. Functions of the Joint Ambulatory Surgical Center Physician Shareholders

Their procedural functions are to:[19]

-Establish a timetable for completion and development of the physician hospital organization
-Select consultants, management specialists, and legal advisors
-Establish a process for keeping physicians and hospitals informed of activities
-Decide when and how all decisions will be made

While, their substantive functions include to:[20]

-Prepare and execute a business plan
-Assess market potential
-Define all mutual goals and objectives
-Create the organizational form and structure
-Negotiate agreements with managed care organizations and other payers
-Form internal and external contracts
-Carry out utilization and quality assurance and assessment
-Handle medical and administrative operations
-Develop financial projections
-Analyze the market for the physician hospital organization by:
-Assessing current contractual relationships of the physicians and hospitals.
-Determining the current market potential for the physician hospital organization with respect to employers, insurers, and patients.
-Providing an all-inclusive review of competing groups already existing or being planned.
-Setting and explaining the required credentialing criteria in case any additional physicians want to join.
-Establishing procedures for medical operations including integration of financial and clinical information systems.

---

[19] James Hall, *Organizational Documents for Integrated Delivery Systems*, The National Health Lawyers Association: Managed Care Law Institute Symposium 1995. For a discussion of how insurers work with integrated healthcare delivery systems to improve quality in healthcare delivery by offering financial incentives, *see* Michelle Mello, et al. *Fostering Rational Regulation of Patient Safety,* 30 J. HEALTH POL. & POL'Y & L. 375 (2005).

[20] *Id.*

II. THE LEGAL RAMIFICATIONS OF THIS TRANSACTION

There are some problems here that need to be remedied or Southern Methodist Hospital's equity interest in the Joint Ambulatory Surgical Center of Tennessee may result in prohibited remuneration under the Anti-kickback Statute.[21] In order to avoid this impropriety, Southern Methodist Hospital must insure that there is no requisite intent to induce or reward referrals, because that will result in the imposition of administrative sanctions, under the *exclusion authority* [22] or the *civil monetary penalty provision* [23] relating to actual commission of acts described. The healthcare lawyer for the hospital may seek an advisory opinion from the Office of the Inspector General if there is any uncertainty about entering into this particular healthcare business transaction.

A. Factors in Regulatory Compliance:

Southern Methodist Hospital provides for a "non-competition" agreement in which it and the physician shareholders are prohibited: (1) from developing and investing in any ambulatory surgery centers offering orthopedic services; (2) from entering into joint marketing arrangements relating to orthopedic services with any hospital system; and (3) from entering into any ambulatory surgery center managed care contracting participation agreement with any provider-sponsored system that competes with Southern Methodist Hospital.[24] The non-competition agreement does not prohibit referrals to or the usage of any other ambulatory surgery center.[25]

B. Southern Methodist Hospital's Governance Over Referrals

The following additional provisions further serve to insure regulatory compliance. Southern Methodist Hospital certifies that the physicians they employ will not make referrals directly to the Joint Ambulatory Surgery Center, but they may refer patients to the physician shareholders. Southern Methodist Hospital will not require or encourage its affiliated physicians to refer patients to the Joint Ambulatory Surgery Center or the physician shareholders. Southern Methodist Hospital will not track referrals made to the Center or its physician shareholders.

---

[21] An arrangement does not violate the Anti-kickback statute if it does not conform to an applicable safe harbor. ANTI-KICKBACK LAW AND STARK II ADVISORY OPINIONS: NEW REGULATIONS DEFINE THE PRICE OF CERTAINTY: American Health Lawyers Association Symposium 2001. *See*, Keri Tonn, *HPSA and the Anti-Kickback Safe Harbor: Are We Sending Doctors to the Right Neighborhoods?* 16 ANN. HEALTH L. 241 (2007).

[22] *See* §1128 (b)(7) of the Social Security Act.

[23] *See* § 1128A (a)(7) and § 1128B(b) of the Social Security Act.

[24] *Id.*

[25] *Id*.

C. Physician Compensation

Southern Methodist Hospital will not directly or indirectly tie hospital-affiliated physicians' compensation to the volume or value of referrals or other business generated by such physicians to the Joint Ambulatory Surgery Center or its physician shareholders. Any compensation will be consistent with fair market value in arm's length transactions. Southern Methodist will notify its physicians of these provisions.

III. ANALYSIS OF THE LEGAL IMPLICATIONS

A. Remuneration: The Anti-kickback Statute, Violations, & Fines

The main legal issue to consider here is the Anti-kickback Statute which makes it a criminal offense "to knowingly and willingly offer, pay, solicit, or to receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program."[26] In other words, the statute is violated when remuneration is purposefully paid to induce or reward referrals of items or services payable by a federal health care program.[27]

Under the statute, criminal liability is extended to both sides in such an unlawful transaction. Further, remuneration includes "the transfer of anything of value, directly, or indirectly, overtly or covertly, in cash or in kind."[28] It is a felony punishable by a maximum fine of $25,000 (imprisonment of up to five years) or both when the statute is violated. Any conviction leads to automatic exclusion from federal health care programs, such as Medicare and Medicaid.[29] Remuneration also covers any arrangement whose main purpose is to obtain money for the referral of services or to induce further referrals.[30]

B. Safe Harbor Regulations

Southern Methodist Hospital and the physician shareholders seek to have their actions classified under the protected class within the "safe harbor" regulations.[31] These safe harbor regulations define practices that are not subject to the Anti-kickback Statute because they do not result in fraud or abuse of the

---

[26] *See* §1128B(b) of the Social Security Act.

[27] *Id.*

[28] *Id*.

[29] The Office of the Inspector General (as authorized under § 1128B (b) of the Social Security Act) may initiate administrative proceedings to impose civil monetary penalties on any party who commits an act in violation of § 1128(b)(7).

[30] *Id*.

[31] *Id*.

healthcare system.[32] It provides that the entity or individual (if it meets certain conditions) will not be prosecuted or sanctioned for any arrangement that qualifies for such safe harbor treatment.[33] There are specific safe harbor regulations relative to Southern Methodist Hospital's investment interest. In this transaction the ambulatory surgical center will be jointly owned by hospitals and physicians and this fact highlights the potential for abuse here.[34] It will be a PHO that is subject to all of the federal regulatory laws.

Southern Methodist Hospital's transaction with the Joint Ambulatory Surgical Center must meet three specific conditions in order to qualify for the safe harbor regulations.[35] First, Southern Methodist Hospital must not be in a position to make referrals directly or indirectly to the Joint Ambulatory Surgical Center. In short, the hospital must not give the appearance that its trying to generate business for the Joint Ambulatory Surgical Center.[36] Second, investing physicians who are also in a position to refer patients to the Joint Ambulatory Center may only invest as individuals (and they must meet the requirements for surgeon-owned ambulatory surgery centers).[37]

Lastly, any services that Southern Methodist Hospital provides to the Joint Ambulatory Center must comply with a safe harbor.[38] For example, it is common for a hospital to provide rental space and other ancillary types of services, however, if the hospital provides space rental for the Joint Ambulatory Surgery Center or management services then to fall under the safe harbor the agreement terms must be for one year.[39]

Further, Southern Methodist Hospital has to be careful to safeguard against potential fraud and abuse in this transaction. It is clearly in a position to influence referrals to the ambulatory surgery center by exerting its control over hospital-affiliated physicians. In order to avoid abuse in this joint venture Southern Methodist Hospital must:

-Refrain from encouraging hospital-affiliated physicians to refer their own patients to the Joint Ambulatory Surgery Center.

-Refrain from requiring hospital-affiliated physicians to make referrals to the center.

-Refrain from tracking referrals made by hospital-affiliated physicians to the center.

-Refrain from tying hospital-affiliated physician compensation to the number of referrals made to the center directly or indirectly.

-Inform its hospital-affiliated physicians of these provisions on a yearly basis.

---

[32] *See* § 1128B(b)(3) of the Social Security Act; 42 C.F.R. § 1001.952.

[33] Under 56 Fed. Reg. 35952, 35954 strict compliance with all elements is required for safe harbor protection.

[34] 42 C.F.R. §1001.952 (r)(4).

[35] 42 C.F.R. §1001.952 (r)(1) - (r)(3).

[36] *Id*.

[37] *Id.*

[38] 42 C.F.R. § 1001.952(b).

[39] *Id*.

C. Professional Ethics

The physician's professional ethics must be taken into consideration when examining the nature and formation of a physician hospital organization. There are issues that arise regarding patient care versus physician's self interest. In this context, those issues stem from the physician's behavior in making referrals. Our public policy dictates that we do not want physician's referring patients for treatment at facilities that they have a financial stake in. It is believed that this will result in unnecessary, excessive, and costlier care. Further, policy wants to ensure the patient does not suffer under this dichotomy, especially if the care rendered is actually painful and turns out to be unnecessary. Finally, the added costs to the system are burdensome and can add to this growing crisis, that healthcare costs continue to outpace inflation. Truly, a physician's sense of professional responsibility does not prevent him or her from profiting in self-referral, or engaging in *over-treatment* solely to make money for themselves. The unlawful referrals section in Stark II seeks to stop these practices that strain our healthcare system.[40]

IV. CONCLUSION AND RECOMMENDATIONS

Clearly, the PHO in general, better protects the consumer from the harmful effects of physician's self-referral and capitation. More cooperation is needed between physician organizations, hospitals, and joint ventures formed; helping to shave costs that have reached astronomical highs.

With a larger group of physicians, costs are spread out more evenly and they face less uncertainty about their practice costs. Therefore, they are less likely to engage in over treatment to make up for losses by year-end. The physician hospital organization fits into that context because the group has the benefit of fiscal balancing with each physicians' costs averaging the other.

The objective of health care reform law is to strike the right balance between cost, control, and quality care. The physician hospital organization and other physician group organizations should play a pivotal role in doing that. The incentive for physicians to band together and cooperate with one another may translate into more effective and ethical delivery of healthcare. Therefore, this is the most useful approach to control costs and to provide healthcare.

---

[40] 42 U.S.C. § 1395nn(a)(1)(A). Stark II covers eleven designated health services and is an expansion of Stark I.