Taking Healthcare's Pulse: Legal Issues Involved in a Healthcare Business Transaction

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Taking Healthcare’s Pulse: The Legal Ethics Involved in Healthcare Business Transactions

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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 deliver healthcare³ and partnerships are being formed between physicians and hospitals. These partnerships add to the marked increase in healthcare business transactions along side the birth and development of the physician hospital organization (“PHO”).⁴ Part I sets forth a hypothetical healthcare business transaction in great detail. Part II analyzes some of the legal implications stemming from the deal. Part III considers and surveys the ethical

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⁴ This paper is limited in scope and will focus on the physician hospital organization (“PHO”). A physician hospital organization (“PHO”) is a kind 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. 170-172 (1988).
issues that physicians face in such transactions. Part IV sets forth the conclusions and recommendations.

The Purpose and Role of a Physician Hospital Organization

The main function of a physician hospital organization is to be 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 they may be a part of a physician’s organization that already has a relationship with the hospital.  

The rationale here is that when a physician hospital organization 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 physician hospital organization 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.  

Formation of a Physician Hospital Organization

The contract for the healthcare business transaction should state what type of entity

5 Thomas M. Gorey, PHYSICIAN ORGANIZATIONS “Cascade Physicians” 55-62.
6 See, generally, Thomas M. Gorey, PHYSICIAN HOSPITAL ORGANIZATIONS.
is being created for example: contractual joint venture, partnership, limited partnership, corporation-for-profit or non-profit, or the limited liability company.\textsuperscript{7} The limited liability company is easily started by filing Articles of Organization with the state and an Operating Agreement which illustrates the governance and operations is also developed.\textsuperscript{8} The advantages of limited liability company are that it combines the tax treatment of a partnership with the limited liability characteristics of a corporation.\textsuperscript{9} There is greater flexibility with this entity in determining the rights and responsibilities of its members.\textsuperscript{10} The hypothetical fact pattern below involves how a physician hospital organization is created using the form of a limited liability company.

Facts

Southern Methodist Hospital is a non-profit, tax-exempt corporation that operates an acute care facility in Tennessee.\textsuperscript{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

\textsuperscript{7} This paper is limited in scope and will focus on the limited liability company as a type of entity that can be chosen. The hypothetical fact pattern deals with a physician hospital organization that is a limited liability company.

\textsuperscript{8} Marilyn Ford, CHARACTERISTICS OF THE LIMITED LIABILITY COMPANY.

\textsuperscript{9} Id.

\textsuperscript{10} Id.

\textsuperscript{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.
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. 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 that are made to the Joint Ambulatory Surgery Center are made with a fair market value interest rate.

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

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 [citations omitted]. 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) as discussed in: Thomas Gorey PHYSICIAN ORGANIZATIONS at 33-43.
Determination of Physician Membership in the Joint Ambulatory Surgical Center

The Physician must agree to the following terms:

(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

Internal Structure of the Joint Ambulatory Surgery Center

Purpose: Compliance with Safe Harbor

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

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\[16\]
\[17\]

\[15\] 42 C.F.R. §1001.952 (p).

\[16\] The sixteen physician shareholders are: Dr. James Phillip Thorpe, Dr. Ellen Ann Smith, Dr. Vincent Michael Soya, Dr. Lynn Victoria Cox, Dr. Stephen R. Lathar, Dr. Susan Marie Mann, Dr. Kurt Max Kent, Dr. Michael Anthony Lewis, Dr. Jean Alexandria Simmons, Dr. Lee Fitzpatrick, Dr. Arthur Isaacson, Dr. John Paleski, Dr. Matthew Milone, Dr. Brian Bixx, Dr. Keith Leonard Nimo, Dr. and Dr. Ted Spec.

\[17\] 42 C.F.R. §1001.952 (r) (1) (ii).
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.

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

18 42 C.F.R. §1001.952 (r) (5).

While, their substantive functions include to:\textsuperscript{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
  - Determine the current market potential for the physician hospital organization with respect to employers, insurers, and patients.

\textsuperscript{20} Id.
- Provide an all-inclusive review of competing groups already existing or being planned

- Set and explain the required credentialing criteria in case any additional physicians want to join

- Establish procedures for medical operations including integration of financial and clinical information systems

The Legal Ramifications of this Transaction:

Southern Methodist Hospital’s Main Legal Concern

Issue

Will this particular healthcare business transaction subject the hospital to legal problems in the form of sanctions and civil fines?

Short Answer

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

\(^{21}\) 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.
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.

Factors in Regulatory Compliance:

The Non-Competition Agreement

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

Southern Methodist Hospital’s Governance Over Referrals

The following additional provisions further serve to insure regulatory compliance.

22 See section 1128(b)(7) of the Social Security Act.
23 See section 1128A(a)(7) and section 1128B(b) of the Social Security Act.
24 Id.
25 Id.
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.

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.

Part II: Analysis of the Legal Implications

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. 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.

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.” 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. Remuneration also covers any arrangement when one purpose is to obtain money for the referral of services or to induce further referrals.

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. These “safe

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26 See section 1128B(b) of the Act.
27 Id.
28 Id.
29 The Office of the Inspector General (as authorized under section 1128B (b) of the Act) may initiate administrative proceedings to impose civil monetary penalties on any party who commits an act in violation of section 1128(b)(7).
30 United States v. Kats, 871 F.2d 105 (9th Cir. 1989).
31 Id.
“harbor” regulations define practices that are not subject to the Anti-kickback statute because they do not result in fraud or abuse of the healthcare system. 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. 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. It will be a physician hospital organization 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. 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 it is trying to generate business for the Joint Ambulatory Surgical Center. 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).

32 See section 1128B (b) (3) of the 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)(2),(r)(3).

36 Id.

37 Id.
Lastly, any services that Southern Methodist Hospital provides to the Joint Ambulatory Center must comply with a safe harbor.\(^{38}\) It is common for a hospital to provide rental space and other ancillary type of services. For example, if the hospital provides space rental for the Joint Ambulatory Surgery Center or management services then the agreement term must be for one year under a safe harbor.\(^{39}\)

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.

\(^{38}\) 42 C.F.R. §1001.952(b).

\(^{39}\) Id.
Part III: Professional Ethic

The physician professional ethic 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 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 more costlier care. The patient can suffer under this dichotomy especially if care is rendered that is actually painful and turns out to be unnecessary. The costs to the system are burdensome and can add to this growing crisis as healthcare costs continue to outpace inflation. Legal experts have argued that physicians’ sense of professional responsibility does not prevent them from profiting in self-referral, or engaging in “over treatment” to make money for themselves. The illegal referrals section in Stark II seeks to stop these practices that tax our healthcare system.

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40 See, Latham, Regulation of Managed Care, supra note 8 at 399.
41 Id.
42 42 U.S.C. §1395nn(a) (1) (A). Stark II covers 11 designated health services and is an expansion of Stark I.
Part IV Conclusion and Recommendations

In conclusion, it is argued here that the physician hospital organization or a physician health organization in general better protects the consumer from the intensive harmful effects of physician self-referral and capitation. Cooperation is needed between physician organizations and hospitals and more joint ventures should be formed because costs are reaching astronomical proportions.

In the article on managed care, Professor Stephen R. Latham argues that, “Plans that spread capitation over groups of five to fifteen physicians are preferable to the consumer.”\(^{43}\) The argument here is that 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. “Cost spreading over multiple physician practices increases certainty; and certainty begets uniformity of decision making.”\(^{44}\)

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

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\(^{43}\) See, Latham, Regulation of Managed Care supra note 8 at 399.

\(^{44}\) Id.
band together and cooperate with one another may translate into more effective and ethical delivery of healthcare. Professor Latham calls for regulations that require “incentive plans to run to groups of physicians rather than to individual physicians.” This seems to be the best approach to control costs and provide needed healthcare.

45 Id.