



**BUSINESS LAW AND GOVERNANCE,
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Hospital/Physician Integration: Three Key Models

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As healthcare reform spurs the industry to focus on cost control and the delivery of high-quality care, improving hospital-physician relationships has taken on a sense of heightened urgency. There is no single hospital-physician integrated delivery model, but, rather, a variety of ways through which to structure these relationships. While many hospitals have pursued alignment strategies with physicians to secure referrals, increase market share and negotiate better rates with commercial payors, hospitals are increasingly competing with each other, surgery centers and large multi-specialty physician practices. Likewise, physicians recognize the negotiating power of larger groups and are increasingly receptive to entering into relationships with hospitals.

This member briefing identifies three models for hospital-physician relationships:

- Co-management service agreements between health systems and physician groups;
- Hospital employment of physicians; and
- Physician-hospital organizations

For each model, the briefing explores structural considerations, regulatory concerns and other implications.

Co-Management Service Agreements

Introduction

A co-management service agreement between a health system and a physician group can provide for the performance of a variety of services, including, for example, medical director services, strategic planning, scheduling and staffing, and human resources duties. These types of arrangements can range from simple relationships amounting to no more than glorified medical directorship agreements to complex structures such as giving the entire profit and loss responsibility of a hospital service line to a physician group. When considering a potential co-management service arrangement, it is necessary to be aware of several potential legal issues that could arise if the arrangement is not structured appropriately. Co-management service agreements must be structured around regulatory considerations that can arise under the federal physician self-referral law, commonly known as the Stark Law, the civil monetary penalty statute (CMP Statute), the Anti-Kickback Statute (AKS), the False Claims Act, an entity's tax-exempt status and Medicare's provider-based requirements. Such agreements also face some antitrust risk, depending on the topics covered by the agreement. This article touches on how each of these regulatory schemes must be accounted for in a co-management service arrangement, but focuses primarily on the legal concerns that arise under the Stark Law. Additionally, this article concludes with a brief discussion of some of the potential business risks and benefits of co-management service arrangements between hospitals and physician groups.

Stark Law and Regulations

Under the Stark Law, a physician may not refer Medicare patients for certain "designated health services" (DHS) where the physician has a financial relationship with the entity to which the patient is referred unless all components of an applicable exception are met.¹ A co-management services agreement between a hospital and a physician group will likely create a financial relationship under the Stark Law. It is

¹ 42 U.S.C. § 1395nn.

possible, however, to structure a co-management arrangement to meet the requirements of either the "fair market value" or "personal service arrangement" exceptions to the Stark Law. A personal service arrangement is generally "an arrangement or multiple arrangements [involving remuneration] to a physician . . . or to a group practice" for the performance of clinical or administrative services.² Of particular note are the requirements related to the compensation paid under a personal service arrangement. In order to fit within the exception, the compensation paid must: (1) be set in advance, (2) not exceed fair market value, and (3) not take into account the volume or value of the physician's referrals.³ A healthcare entity can address Stark Law risks that arise in relation to a co-management service arrangement by setting the base and bonus fees paid to the physician group providing services under the arrangement according to the following guidelines.

Base Fee for Services

The base fee for administrative services provided to a hospital by a physician group under a co-management service agreement may be set according to the following guidelines in order to ensure that the base fee complies with the requirements of the personal service arrangement exception to the Stark Law:

- The parties to the agreement should obtain an independent appraisal of the fair market value of the administrative services whether paid on an hourly basis or by fixed fee to ensure the amount reflects the fair market value hourly rate; and
- The physicians providing services under the agreement should be required to track by the hour the time they spend providing the administrative services required under the agreement.

² 42 C.F.R. § 411.357(d)(1).

³ 42 C.F.R. § 411.357(d)(1)(v).

Bonus Fee for Meeting Quality Thresholds

In addition to a base fee, co-management service agreements may be structured to include a bonus fee that is paid for meeting or exceeding quality-related thresholds or benchmarks. Bonus fees based upon quality performance measures as opposed to, for example, volume or revenue-based performance measures, can be drafted to comply with the Stark Law. Benchmarks related to the payment of a bonus fee under a co-management service agreement should be focused on objective quality indicators and not on subjective indicators or indicators that are significantly tied to cost reduction or revenue increases. Similar to the base fee, the bonus fee should be structured to reflect the fair market value of the services provided by the physician group and set in advance to reward improvement based upon objective quality metrics. Engagement of an independent valuation company is a highly recommended step in determining the bonus fee rate. Even though the bonus fee can be paid for meeting established quality thresholds, a preferred method is for the hospital and physician group to project the number of hours the physician group will need to work to meet each threshold.

Anti-Kickback Statute

A co-management service agreement between a health system and a physician group can create risks under the AKS, which prohibits knowingly and willfully paying to induce referrals for services paid for by federal healthcare programs.⁴ To reduce anti-kickback risks, a co-management service agreement should never tie compensation to the volume or value of referrals. Likewise, rewards should not be given for achievement of measures related to revenues or patient or payor mix. Again, an independent appraisal of the fair market value of the services provided under the co-management arrangement is recommended as it will provide some security against any inference that the payments contemplated by the arrangement are intended to induce referrals for services paid for by federal healthcare programs.

⁴ 42 U.S.C. § 1320a-7b(b).

Civil Monetary Penalty Statute

The CMP Statute prohibits hospitals from making payments to physicians directly responsible for patient care that might have the effect of reducing or limiting services to Medicare or Medicaid beneficiaries.⁵ Often, hospitals will seek to structure co-management service agreements to include gain-sharing arrangements, but this would implicate the CMP Statute. However, bonus fees awarded for the achievement of objective quality measures, as discussed above, and contemplated as an element of a co-management service agreement are not the type of arrangements that would typically implicate the CMP Statute as long as the benchmarks affecting the amount of the bonus fee are not based upon cost reductions.

Other Legal Concerns

In addition to potential issues under the Stark Law and regulations, the AKS and the CMP Statute, healthcare entities considering entering into physician group co-management service agreements should be aware of the following other legal issues:

False Claims Act

Violations of the Stark Law and the AKS can form the basis of liability under the False Claims Act.⁶

Tax-Exemption Under Internal Revenue Code §501(c)(3)

One requirement for tax-exempt status is that compensation paid by a tax-exempt entity be reasonable. An independent valuation of the services provided under a proposed co-management service arrangement would be helpful in establishing the reasonableness of the compensation paid for the services provided under the arrangement.

Provider-Based Status Requirements

⁵ 42 U.S.C. § 1320a-7a(b).

⁶ 31 U.S.C. § 3729-3731.

Restrictions apply under the provider-based rules where a co-management service agreement covers management services provided off a hospital's main campus.⁷ In order to meet the requirements of the provider-based status rules, such an arrangement must have among other characteristics the following: (1) the management services must be provided at a location within 35 miles of the main hospital; (2) the main hospital must employ certain clinical staff at the off-site location; and (3) the main hospital must have administrative, financial and clinical control of the off-campus services.

State Law

Depending on the location in which the parties are located, various state specific regulatory considerations may need to be accounted for in structuring a co-management service arrangement.

Antitrust Issues

Depending on their substance, co-management service agreements might also implicate the antitrust laws. Most significantly, if the agreement results in competitors sharing competitively sensitive information like price and salary information, that sharing could violate the antitrust laws when it facilitates interdependent pricing decisions, or the sharing could serve as circumstantial evidence of an alleged conspiracy to fix prices.⁸ The Healthcare Statements provide guidance on sharing pricing information among competitors.⁹ Perhaps more remotely, a hospital that “outsources” any part of its credentialing decisions (whether intentionally or not) to a physician group opens itself to a claim of an antitrust conspiracy by an excluded provider.¹⁰

⁷ 42 C.F.R. §413.65(h).

⁸ E.g., *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001); *Jung v. Ass'n of Am. Med. Colls.*, 300 F. Supp. 2d 119, 167 (D.D.C. 2004).

⁹ Health Care Statement 6.

¹⁰ See, e.g., *Oltz v. St. Peter's Cmty. Hosp.*, 861 F.2d 1440 (9th Cir. 1988).

Business Risks and Benefits of Co-Management Service Arrangements

Market forces, healthcare reform and decreasing reimbursement continue to push physician groups away from traditional private practice toward closer alignment with hospital systems. Co-management service arrangements can allow physician groups to become more closely aligned with a hospital system while retaining a level of independence. The operational risks associated with such arrangements can be minimized by making sure that the parties' enter into a co-management service agreement that clearly describes what the hospital is willing to let the physician group manage and the specific tasks and functions the physician group will be responsible for performing. A quality co-management service agreement should reflect a clear understanding between the hospital and the physician group as to the effect the hospital's retained governance authority will have on the physician group's ability to perform the management services it is responsible for under the agreement. Provided the parties to a co-management service agreement clearly understand their respective rights and responsibilities, the arrangement contemplated by the agreement can have the benefit of enhancing the physician group's satisfaction with its hospital alignment by allowing it to participate in the operational and strategic efforts of the hospital. The hospital on the other hand can gain from possible cost reductions and securing the services of a valuable physician group in an important service line of the hospital.

Co-management service arrangements are complex and require significant planning to comply with the various federal regulatory requirements contained in the Stark Law, the AKS, the False Claims Act, provider-based requirements, the CMP Statute and tax-exempt laws. Despite these complexities, well structured co-management service arrangements can have significant benefits for both the hospitals and physician groups. Additionally, co-management service arrangements can help physician groups and hospitals avoid the shortcomings of other hospital-physician alignment models such as physician employment and gain-sharing. Specifically, co-management service agreements can often be implemented quicker and more economically than physician

employment and gain-sharing arrangements and can give physician groups a greater ability to implement broader changes to improve productivity and a road to significant alignment with a hospital system that may be acceptable in situations where a move toward hospital employment would be difficult to achieve.

Hospital Employment

Introduction

The national trend toward hospital employment of physicians continues to grow. The looming scarcity of primary care physicians (and certain other specialty physicians) fuels hospitals' competitive need to ensure the adequacy of their provider networks, and the mantra of "work-life balance" for younger physicians entering the workforce encourages them to seek employment by another entity instead of ownership in a medical practice. Alignment of physicians' and hospitals' interests has long been a goal but recent quality initiatives, Pay-for-Performance (P4P), and healthcare reform have all heightened its importance. Physician employment by hospitals is probably the most straight forward means of addressing both the market pressures and the impending changes in the payment system.

This member briefing describes existing hospital-doctor employment models, including alternatives to direct hospital employment, legal and regulatory issues, and considerations involved where hospitals acquire physician practices.

Legal Structure and Governance Options

Direct Hospital Employment

In many states, hospitals can directly employ physicians. When there are no state statutory prohibitions, direct employment is the simplest model to implement. Where a physician has an existing private practice, the hospital (or a hospital affiliate) may purchase the practice as a prelude to employment.

From the hospital's standpoint, direct employment permits the greatest degree of integration to achieve its goals of implementing uniform best clinical practices, measuring clinical outcomes, developing P4P payor contracting relationships, establishing unified Health Information Technology (HIT) solutions, and improving physician recruiting and retention, as well as obtaining higher reimbursement by billing the physician office and ancillary services as provider-based rather than as a freestanding practice. As discussed below, the direct employment model is the most effective way of meeting Stark Law exceptions and AKS safe harbors for bona fide employment relationships.

Foundation Model

The Foundation Model may be utilized in states with corporate practice of medicine laws that prohibit direct employment (e.g., California and Texas). In the Foundation Model, a hospital creates, but does not own, a nonprofit medical foundation, which owns and operates the physician clinics. Typically, the hospital controls the medical foundation's governing board and obtains tax-exempt status for the medical foundation under Internal Revenue Code (IRC) § 501(c)(3). The clinics arrange for physician services with one or more physician practices through professional services agreements (which are independent contractor arrangements). The physician practices, rather than the clinic, foundation, or hospital, employ the physicians.

The Foundation Model has become popular in California, where state laws preclude most hospitals from directly employing physicians. Examples of the Foundation Model in California include Cedars-Sinai Medical Care Foundation, Sutter Medical Foundation, Scripps Health Foundation, and the Rady Children's Hospital Foundation.¹¹

¹¹ To date, the key component of the Foundation Model in California has been that the nonprofit foundation operates the clinics for the physicians. A variation of that model has been challenged in *California Cancer Specialist Medical Group, Inc. v. City of Hope National Medical Center*, filed in Superior Court, Los Angeles, Central District, May 13, 2010.

Subsidiary/Affiliated Entity Models

The Subsidiary/Affiliated Entity Models are best described as “transitional” models that hospitals and physicians may use to align themselves prior to attempting to integrate fully through direct employment. These models differ from the classic direct employment models in that they are structured with one or more intermediate entities, and they establish compensation based on the practice’s bottom line financial success. The goal is to combine the best attributes of private practice with the proven benefits of an integrated group practice. The use of a separate legal entity for employment also allows the physician practice to meet the Stark Law definition of a “group practice,” which permits the provision of ancillary services within the entity as well as the inclusion of ancillary service revenue/profit in the physician compensation plan – an advantage over direct hospital employment for the physician.

-Physician Enterprise Model- The Physician Enterprise Model is designed to address physicians’ concerns about selling and relinquishing control over day-to-day operations of their practices. In the Physician Enterprise Model, a hospital employs physicians through a separate, but affiliated, legal entity that is formed as a “group practice” for the Stark Law and other regulatory purposes (Physician Enterprise). The physicians are bona fide employees of the Physician Enterprise for the purposes of IRS, the Stark Law and AKS requirements.

The principal element of the compensation plan is usually payment of compensation based on the individual allocation of the Physician Enterprise’s excess revenue over its expenses. The goal is to have the compensation model look and feel like a private physician practice, with incentives to grow revenue and control expenses. This differentiates it from direct hospital employment with guaranteed salaries. The hospital does not buy the physicians’ practice assets. Instead, the physicians retain ownership

and manage the Physician Enterprise, providing administrative services, non-physician support staff, facilities, equipment, furnishings, etc., to the Physician Enterprise under a management services agreement that complies with the Stark Law, AKS, and state physician self-referral laws. The Physician Enterprise, although a hospital subsidiary, may or may not seek tax-exempt status depending on the level of physician governance in the entity (see discussion below).

-Affiliated Professional Entity- The hospital private practice group model (or Affiliated Subsidiary Model) is a variation of the Physician Enterprise Model and may be used by a hospital to establish separate group practices for different service lines. Under this model, the hospital usually establishes a new nonprofit, *taxable* corporation (due to the expanded physician governance rights discussed below) as a wholly-owned subsidiary of the hospital or its health system entity.

Alternatively, in states with strong corporate practice of medicine laws, the entity may be formed as a “friendly” or “captive” professional corporation or other professional practice entity with the sole shareholder being another full-time physician hospital employee. The structural, operational and, to some degree, financial control over the practice entity, its shareholders, and directors may then be conveyed to the hospital by means of any number of documents and agreements, including an administrative services agreement, a stock transfer restriction agreement (to ensure a hospital-friendly successor), as well as the practice entity’s charter and bylaws. The captive practice entity then employs the physicians whom the hospital could not employ directly.

The Affiliated Subsidiary Model contemplates expanded physician governance rights not typically found in a hospital subsidiary, including allowing physicians to have majority control of the Board, with certain reserve powers remaining under the control of the hospital (see “Joint Governance Option” below). Each physician enters into an employment agreement with the subsidiary, with the principal compensation element

consisting of payment of compensation based upon the individual allocation of the subsidiary's excess revenue over its expenses. Initially, the subsidiary provides the same or substantially the same benefit package and current compensation to its physician employees as was in place through the private practice group(s). The board of directors of the subsidiary approves a uniform benefit package applicable to all physicians, notwithstanding any differences between the benefit packages of the groups prior to the effective date of employment. As with the Physician Enterprise Model, this model does not include the purchase of any practice assets from the groups, and uses a compensation model that looks and feels like a private physician practice, with incentives to grow revenue and control expenses.

-Physician Leasing Model- The Physician Leasing Model is a service agreement model that allows physicians to remain independent practitioners within their existing practice entity. Under this model, the hospital contracts with large group practices for consolidated service lines, such as cardiology or orthopedic surgery, to provide clinical and/or administrative services. Under the contract terms, the practice entity leases all or substantially all of its physician (and sometimes non-physician) employees to the hospital to provide services on behalf of the hospital, and the hospital has sufficient control over the physicians' rendering of services so that the hospital may properly bill all governmental and non-governmental third party payors for the services provided by the physicians. The hospital bills payors for the services, retains all collections from such billings, and pays fixed fair market value fees to the practice entity for the services. The fee structure may also include legally appropriate incentive arrangements. The fixed amounts can be structured as an independently determined fair market value fixed compensation amount per full-time equivalent (FTE) physician. This lease arrangement can be structured to comply with the Stark Law's personal service arrangements or fair market value exceptions and the AKS personal services arrangement safe harbor.

Governance Options

-Hospital-Directed Option- Hospital-directed governance exists where the relationship between the hospital and the physician is a traditional employer/employee relationship. The employing hospital dictates the terms for the physician's employment, arranges scheduling, provides support staff, conducts billing, and so forth. If the employment is through a physician practice subsidiary entity, this option provides the best chance to obtain tax-exempt status for the practice entity.

-Joint Equity Option- Joint equity options would typically be involved where a hospital chooses to acquire an ownership interest in an existing medical practice through a designated "friendly" physician employee, as opposed to an asset purchase transaction. An example of this model for ownership and governance was described in the AHLA Executive Summary, [*Affiliation of Swedish Medical Center and Minor & James Medical*](#), B. Eller, March 2010.

-Joint Governance Option- Hospitals may choose to give physicians meaningful participation in the governance structure, even where the physicians do not have any ownership interest in the physician practice entity that employs them. This approach is evident in the governance structure used in the Affiliated Subsidiary and Physician Enterprise Models, where both the hospital and the physicians designate a certain number of directors to the entity's board of directors and, in some cases, physicians may represent a majority of the board. On the other hand, certain designated matters are reserved to the sole approval of the hospital, such as sale of the practice, while certain other major actions, such as approval of budgets, are subject to approval by majority vote of both the physician directors and the hospital directors, with appropriate dispute resolution and deadlock procedures in the governance documents.

Federal and State Regulatory Considerations

A hospital's acquisition of a physician practice and its subsequent employment of the practice's physicians raise federal and state regulatory considerations. The Stark Law, the AKS, and the IRC all contain restrictions or limitations on the hospital-physician employment relationship. In addition, state corporate practice of medicine and referral prohibitions may limit the parties' ability to contract or affiliate with one another. Finally, such an acquisition could run afoul of antitrust laws if it would result in the hospital having market power in a properly defined market.

The Stark Law

The Stark Law generally prohibits a physician from referring Medicare or Medicaid patients for DHS, including hospital inpatient and outpatient services, to an entity with which the physician or a member of the physician's immediate family has a financial relationship, unless the referral meets an exception under the statute or regulations.¹² When a hospital acquires a physician practice and then employs the practice's physicians, each arrangement must meet an exception to the statutory prohibition.

-Physician Practice Acquisition- The sale of a physician practice to a DHS entity (such as a hospital) can be made under the "isolated transaction" exception to the Stark Law rules¹³ if: (1) the purchase price is fair market value and does not take into account (directly or indirectly) the volume or value of any referrals by the physicians in the physician practice to the purchaser, (2) the transaction would be commercially reasonable even if there were no referrals by the physicians in the practice to the purchaser, and (3) there are no additional financial relationships between the parties for six months after the transaction (other than certain post-closing adjustments) unless the additional relationships meet another Stark Law exception.¹⁴

¹² 42 U.S.C. § 1395nn(a)(1). The Stark Law also prohibits a DHS entity from presenting or causing to be presented a claim to anyone for a DHS furnished as a result of a prohibited referral.

¹³ *Id.*

¹⁴ 42 C.F.R. § 411.357(f).

Under the isolated transaction exception, installment payments are permissible as long as the total maximum payment in the aggregate is fixed before the first payment is made and does not take into account (directly or indirectly) the volume or value of referrals or other business generated between the physician and the purchaser, and the required payments are secured in the event of a default by the purchaser. To this end, the parties may select from several options, including immediately negotiable payments or payments guaranteed by a third party, or payments secured by a promissory note.¹⁵

-Employment- After a hospital acquires a practice and the physicians have agreed to hospital employment, the parties' financial arrangement with respect to such employment must comply with a Stark Law exception. The Stark Law's employment exception permits a physician's bona fide employment by a hospital (i.e., the entity to which he or she refers DHS) if: (1) the employment is for identifiable services, (2) the compensation is consistent with the fair market value for the services rendered and is not determined in a manner that takes into account, directly or indirectly, the volume or value of the physician's referrals, and (3) the employment contract would be commercially reasonable even if no referrals were made to the DHS entity.¹⁶ In such a case, the hospital may provide the physician employee a productivity bonus, but only if such bonus is based on the services personally performed by the physician.

If the hospital were to establish a dedicated subsidiary to employ the physicians, that subsidiary could qualify as a "group practice," in which case the subsidiary would have additional flexibility in compensating its physicians for their performance. For instance, physicians in the group practice could receive a share of overall profits of the group as

¹⁵ 42 C.F.R. § 411.351 (definition of "transaction").

¹⁶ 42 C.F.R. § 411.352(c).

long as the profit sharing or bonus is not determined in a manner that “directly” relates to that physician’s volume or value of referrals.¹⁷

Many states also have their own physician self-referral prohibitions. Generally, state laws are less specific than the Stark Law and little guidance or interpretation regarding their application may exist.

The Anti-Kickback Statute.

The AKS provides for criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce a referral or recommend the referral of an individual to another person or entity for the furnishing or arranging for the furnishing of any item or service that may be paid in whole or in part by any federally funded healthcare program.¹⁸ For purposes of the statute, “remuneration” includes the transfer of anything of value, including cash, free goods, services, discounts, or items priced below fair market value.¹⁹

The AKS is broad in scope, and its penalties are severe. When liberally interpreted, otherwise beneficial and common arrangements can be construed as violating the statute. Therefore, Congress directed the United States Department of Health and Human Services’ (HHS) Office of Inspector General (OIG) to promulgate regulations that create “safe harbors” for various business transactions and payment practices that would not be the subject of criminal prosecution under the statute and that would not

¹⁷ 42 C.F.R. § 411.352(i). Note that CMS has proposed a “stand in the shoes” rule for DHS providers that would change the analysis in a hospital-owned subsidiary mode since a hospital that has a subsidiary that employs a physician will be deemed to stand in the shoes of the subsidiary, which will cause there to be a direct financial relationship between the hospital and the employed physician.

¹⁸ 42 U.S.C. § 1320a-7b(b).

¹⁹ See, e.g., Department of Health and Human Services Office of the Inspector General (OIG) Advisory Opinion No. 10-08 (June 10, 2010). Responsibility for enforcement of the AKS is shared between the OIG and the Department of Justice.

form a basis for civil monetary penalties or Medicare/Medicaid exclusion proceedings.²⁰ Transactions that do not satisfy every element of a safe harbor are not *per se* illegal; rather, enforcement agencies may subject those transactions to greater scrutiny and could determine that they violate the AKS.²¹

-Hospital-Physician Employment- The AKS does not prohibit, and specifically excludes from the definition of “remuneration,” payments made by employers to their bona fide employees for the furnishing of items or services that may be reimbursable by a federal healthcare program.²² For purposes of this safe harbor, the term “employee” has the definition assigned to it in the IRC.²³ Thus, in addition to complying with the employment exception under the Stark Law, which, as previously noted, requires (among other things) an agreement that sets forth the compensation that is consistent with fair market value and does not take into account the value or volume of referrals, hospital employers must ensure that their physician employees constitute bona fide employees as defined by the Internal Revenue Service (IRS).²⁴

-Physician Practice Acquisition- Where a hospital acquires a physician practice, there is no safe harbor with which the parties can comply unless the practice is located in a health professional shortage area.²⁵ When a transaction does not meet each of the

²⁰ The OIG also issues advisory opinions to requesting organizations to determine if under a particular set of facts (as described by the requestor) the arrangement between two or more entities would violate the AKS. In addition to analyzing a hospital-physician practice acquisition for compliance with the AKS, the OIG has frequently expressed concern about whether hospitals are complying with provider-based designation requirements for purchased physician practices. Generally, hospitals have two options as to how to account for their purchased physician practices: treat them as free-standing and utilize the Physician Fee Schedule for purposes of Medicare reimbursement, or treat them as part of the hospital, also known as provider-based, and obtain reimbursement for non-physician services at the practice under Medicare’s outpatient hospital PPS, which is typically higher than for a free-standing physician office. Hospitals that treat their purchased practices as provider-based need to make sure they are meeting the federal requirements to obtain that designation or risk allegations of improper billing.

²¹ See 56 Fed. Reg. 35952, 35955 (July 29, 1991).

²² 42 C.F.R. § 1001.952(i).

²³ *Id.*

²⁴ See 26 U.S.C. § 3121(d)(2).

²⁵ The safe harbor relating to practice acquisitions by hospitals applies only to practices located in a health professional shortage area (42 C.F.R. § 1001.952(e)(2)). There is also a safe harbor for other practice acquisition but it applies only to a sale from one physician to another (see 42 C.F.R. § 1001.952(e)(1)).

safe harbor elements, the likelihood of enforcement will depend on numerous factors, including whether: (1) a safe harbor does not exist to capture an otherwise innocuous arrangement, (2) a good faith effort was made to comply with a safe harbor's requirements, and (3) the arrangement was intended to induce referrals.

In reviewing purchases of physician practices by hospitals, the OIG has indicated that it will review the price paid for a physician practice in its analysis of determining whether there was an intent to pay for future referrals from the physicians in question.²⁶

Internal Revenue Code

In addition to Stark Law and AKS considerations, nonprofit hospitals must take into account their tax-exempt status when purchasing for-profit physician practices and subsequently employing their physicians. Pursuant to Section 501(c)(3) of the IRC, a tax-exempt entity must be "organized and operated exclusively for religious, charitable, scientific...or educational purposes."²⁷ In addition, no part of the tax-exempt entity's net earnings may inure to the private benefit of any individual.²⁸ Both the "private benefit" and "private inurement" prohibitions are implicated in a hospital's acquisition of a physician practice and employment of the physicians.

The "private benefit" prohibition precludes the income or assets of a tax-exempt organization from being transferred away from the organization to one or more outside individuals. The private benefit that flows to an individual must be substantial in order to jeopardize the entity's 501(c)(3) status. By contrast, when an "insider" receives an excess economic benefit, it is called "inurement," and under a five-factor, all-the-facts-

²⁶ OIG Letter to IRS (December 22, 1992) *available at* <http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm> (last accessed October 29, 2008).

²⁷ 26 U.S.C. 501(c)(3).

²⁸ *Id.* See also 26 C.F.R. 1.501(c)(3) -1(c)(2).

and-circumstances analysis set forth in the Treasury Regulations, that inurement may lead to revocation of the entity's tax-exempt status.²⁹

Where a nonprofit hospital acquires a physician practice and subsequently employs the practice physicians, a private benefit will be found if the hospital pays more than fair market value for the practice or as compensation for the physicians' services. Fair market value is defined as the price on which a willing buyer and a willing seller would agree, neither being under any compulsion to buy or sell, and both having reasonable knowledge of the relevant facts.³⁰ Generally, when a transaction involves parties with no relationship to one another, the sale price may be assumed to be fair market value. When hospitals acquire physician practices, however, the practices tend to be comprised of physicians on the medical staff (or soon to be on the medical staff), or who will otherwise provide services to the hospital in some capacity on a going-forward basis, and therefore they are considered "insiders." In this instance, the existence of an arm's-length transaction may be called into question, and ensuring that both the purchase price for the practice and the physicians' compensation are fair market value and not excessive consideration will be key to avoiding the potentially severe legal consequences of tax-exempt status revocation.³¹

²⁹ See Treas. Reg. § 1.501(c)(3)-1(f). The five-factor test considers the following: (i) the size and scope of the organization's regular and ongoing activities that further exempt purposes before and after the private inurement transaction occurred; (ii) the size and scope of the private inurement transaction in relation to the size and scope of the organization's regular and ongoing activities that further exempt purposes; (iii) whether the organization has been involved in multiple private inurement transactions with one or more persons; (iv) whether the organization has implemented safeguards that are reasonably calculated to prevent private inurement transactions; and (v) whether the amount of the excess economic benefit has been repaid to the organization, plus interest at the applicable federal rate, or whether the organization has made good faith efforts to seek return of the excess amount, plus interest, from the insider who benefited from the private inurement transaction. Depending on the particular situation, the IRS may assign greater or lesser weight to some factors than to others.

³⁰ Rev. Rul. 59-60, 1959-1 C.B. 237.

³¹ Recognizing the harshness of the "de minimis" rule wherein an organization's tax-exempt status can be revoked if it engages in a transaction that inures to the benefit of an insider, Congress established the "intermediate sanctions regulations," which are designed to penalize the individuals, rather than the organization as a whole, who approved excess compensation transactions that led to private inurement. See Treas. Regs. Subchapter D, Sec. 53.4958.

State Corporate Practice of Medicine Issues.

There are other legal considerations to consider beyond the fraud and abuse, self-referral, and tax-exempt implications in the hospital employment model. Importantly, hospitals and physicians entering into employment relationships must ensure that state corporate practice of medicine laws do not prohibit such arrangements. The corporate practice of medicine doctrine generally prohibits corporate entities from directly employing physicians. The doctrine's underlying theory is that it protects patients from the potential abuses of commercialized medicine, which causes physicians to divide their loyalties between profits and the delivery of quality patient care.

Although most corporate practice of medicine states specifically exclude hospital employment of physicians from their corporate practice of medicine bans, other states, such as California and Texas, consider most hospitals to be corporate entities that cannot directly employ physicians. In these strict corporate practice of medicine states, hospitals and physicians must engage in alternative arrangements that do not run afoul of the prohibition.³² For example, many hospitals create “friendly” or “captive” professional corporations (P.C.) where the captive P.C. employs the physicians whom the hospital cannot directly employ.³³

Antitrust Issues

Hospitals acquiring physician practices and employing the physicians in those practices might also draw the attention of the antitrust enforcement agencies (the Department of Justice and the Federal Trade Commission). The enforcement agencies may scrutinize the transaction even if the acquisition is not one that is reportable under the federal

³² Although the captive P.C. model helps hospitals and physicians satisfy the literal requirements of the corporate practice of medicine prohibition, it raises other issues, including how to distribute profits to the hospital without jeopardizing its tax-exempt status.

³³ Many hospitals in corporate practice of medicine states will also use the captive P.C. model, even though direct physician employment is permissible, since hospital ownership of professional corporations is prohibited.

Hart-Scott-Rodino Act.³⁴ The agencies will look for indicia that the acquisition would give the hospital “market power” in a well-defined geographic and product market. Market power is the ability to raise prices above the rate that would prevail in an otherwise competitive market. The agencies will consider a wide range of direct and circumstantial evidence to determine whether the hospital would obtain market power as a result of the acquisition, including the preexisting market shares of the hospital, the target physician group, and their competitors in relevant service lines; the ability of new competitors to enter the market and existing competitors to expand their services; the reaction of third-party payors to the proposed acquisition; the parties’ own internal documents; and market analyses and other documents prepared by the parties and their consultants. The parties to a proposed transaction that might result in market power on behalf of the hospital should be prepared to demonstrate any offsetting pro-competitive efficiencies relating specifically to the acquisition. Such efficiencies could include demonstrable increases in quality; reduced utilization through integrated care; the ability to introduce new service lines; and the ability to invest in new technologies (like electronic medical records systems), all of which would not be possible but for the acquisition.

Acquisition of Physician Practices

Where a hospital is entering into direct employment arrangements with physicians in existing practices, the hospital typically purchases the group practice. The purchase is much like that of any business, with the addition of the regulatory issues unique to healthcare and the relationships between hospitals and physicians. This section highlights many of those unique regulatory issues.

³⁴ Under section 7A of the Clayton Act, as added by Hart-Scott-Rodino, mergers and acquisitions of a certain size must be reported to the enforcement agencies and must wait a minimum of 30 days before closing so the agencies may review the transaction. 15 U.S.C. § 18a. The threshold amounts are adjusted annually.

Structure of Transaction

There are primarily two transaction structures for the purchase of physician transactions: (1) the purchase of substantially all of the physician practice assets (Asset Purchase), which is typically more advantageous to the hospital, and (2) the purchase of the capital stock of the physician practice professional corporation (Stock Purchase), which is typically more advantageous to the physician practice.

With an Asset Purchase, the hospital may achieve certain tax benefits because of its opportunity to step-up the tax basis of the purchased assets to fair market value. This option also allows the hospital to identify, then pick and choose, the liabilities of the physician practice that it wishes to assume. This liability insulation aspect is sometimes the most compelling reason why hospitals prefer the Asset Purchase structure.

Under the Stock Purchase structure, the hospital purchases the professional corporation in its entirety and, thus, all of its assets and liabilities. Some state statutes restrict the ownership of professional corporations by shareholders other than physicians, however. One way to structure around these restrictions is to convert the professional corporation to a business corporation at the time of closing of the transaction, subject to the corporation laws of each state. Physicians may enjoy tax benefits with the Stock Purchase because usually there is only one layer of tax in the sale and the stock sale receives capital gains treatment in most instances. The tax attributes of each transaction should be reviewed on a case-by-case basis based on the particular situation.

Purchase Price Considerations

-Regulatory Considerations- As discussed above, Stark Law, AKS, and similar state laws come into play with regard to price considerations.³⁵

³⁵ The AKS is found at 42 U.S.C. § 1320a-7b (2008); 42 C.F.R. § 1001.952 (2008). The Stark rules are found at 42 U.S.C. § 1395nn (2008); 42 C.F.R. Part 411 (2008).

In its letter dated December 22, 1992, the OIG provided guidance on the proper method for valuing a physician practice (the 1992 OIG Letter).³⁶ The OIG stressed in the 1992 OIG Letter that a hospital's payment for a physician practice will implicate the AKS if the amount paid for the practice was made with the intent to induce patient referrals. The amounts paid for the physician practice must reasonably reflect the fair market value of the practice. If the price exceeds fair market value, then the OIG will likely infer that the excess price was made to induce patient referrals.

The OIG has stated that any amount paid that exceeds the fair market value of the practice's hard assets would be open to question, including payments made for goodwill, noncompetes, the value of an ongoing business unit, exclusive dealing arrangements, patient lists, and patient records, because such payments may be viewed as payment for the value of a referral stream. Although the 1992 OIG Letter raises concerns over including intangible assets in the practice valuation, including such intangible asset valuations are not *per se* illegal under the AKS.³⁷ The intent of the parties, demonstrated primarily through the fair market value nature of the payments, is the central inquiry in determining whether the AKS has been violated. Because the valuation is critical to regulatory compliance, obtaining a proper valuation opinion from a reputable independent healthcare valuation firm that supports the purchase price being paid has become standard in the purchase of physician practices.

-Other Valuation Considerations- When determining fair market value, valuation firms will use three primary valuation methods: (1) the asset value approach; (2) the market approach; and (3) the income approach. Because the purchase prices in physician

³⁶ OIG Letter to IRS (December 22, 1992) *available at* <http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm> (last accessed October 29, 2008).

³⁷ OIG Letter to the American Hospital Association (November 2, 1993) *available at* <http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition110293.htm> (last accessed October 29, 2008).

practice sales are typically not made public, the market approach is difficult to use. In addition, because of regulatory concerns in certain situations, many hospitals are reluctant to use the discounted cash flow method of the income approach in determining physician practice value. This valuation method also can produce a large amount of goodwill, which can lead to heightened regulatory scrutiny. The income approach often yields the highest value of the three valuation approaches (where adjustments are made to net income to calculate a true business cash flow).

To date, the safest valuation approach from a regulatory standpoint has been the asset value approach. When using this approach, the hospital will argue for a low value on intangible assets, while the physician practice will push for a higher value on intangibles. Values for intangibles are typically assigned to: (1) the assembled work force, (2) the practice location and reputation, and (3) the active medical records of the practice. Again, although including intangible asset values is not *per se* illegal under the AKS, under the 1992 OIG Letter, the value assigned to intangible assets will be subject to a higher scrutiny by the regulatory authorities.

-Considerations Regarding Noncompetition Covenants- In virtually all hospital purchases of physician group practices, the hospital will want certain noncompetition/ nonsolicitation covenants from both the practice group entity and the underlying physicians. There are typically two types of noncompetition covenants.

The first noncompete covenant relates to the purchase agreement and normally has a duration of between two to five years from the closing date of the purchase. The second noncompete covenant is associated with the physician employment agreement and is contained in those agreements. Its duration typically lasts through the term of employment and between one to two years after the employment ends.

It should be noted that many states restrict the enforceability of noncompetition covenants for physicians and their practice of medicine. Even in these states, however, the hospital can usually enforce a noncompetition covenant relating to the ownership or management of ancillary service businesses or the association of the physicians with those types of ancillary businesses. The noncompetition territories associated with these noncompetition covenants must be reasonable in scope, and typically encompass the market area of the particular hospital and the physician office locations and can vary widely between rural and urban areas. For example, a territory of 5 to 30 miles from the hospital and each physician practice location is often seen in these types of restrictive covenants.

-Physician Repurchase Provisions- Physicians are reluctant to cede control of their practices to a purchasing hospital without some type of “unwind” provision in the purchase agreement that allows the physicians to repurchase their practice from the hospital if the relationship does not go well. Under these arrangements, the physician group will have the opportunity to repurchase the assets of its practice from the hospital (almost always at fair market value at the time of future purchase) if a certain percentage of the physicians vote in favor of the repurchase. Often, the hospital will require that the physicians’ right to repurchase is not triggered until a certain time period has passed following the physician practice purchase by the hospital (e.g., three years). These repurchase rights can be for a limited duration of time (for example, the right could remain in place for a period of 90 days after the fifth anniversary of the physician practice purchase), or for an unlimited duration (the repurchase right could remain in place indefinitely following the third anniversary of the physician practice purchase). These repurchase provisions provide the physicians with an “escape hatch” and give the physicians more comfort in entering into the sale of their practice at the outset. Unwind provisions may also deal with such issues as to who has rights to accounts receivable for services rendered prior to the unwind, who will employ non-physician personnel, who will assume practice office leases and how electronic billing and medical record information will be transitioned.

-Employment of Non-Physician Personnel- In sales of physician practices, the physicians will normally want to ensure the job security of the non-physician personnel employed by the physician group. The physicians typically will require the hospital to hire all of the non-physician personnel with substantially similar compensation and benefit packages provided by the physician practice. The request for consistent compensation and benefits by the physicians can sometimes cause challenges for the hospital, especially when the hospital has a differing set of salary levels and benefit packages for like personnel at the physician group. The physician group will also generally request that the hospital grant “years of service credit” for the physician group employees for purposes of the benefit plans of the hospital.

One issue that will need to be resolved relating to personnel of the physician practice is whether the accrued paid time off (accrued vacation and sick days) will be assumed by the hospital, and if assumed, whether the value of such accrued paid time off will be deducted from the purchase price paid to the physician group. Accrued paid time off provisions are the subject of negotiation between the hospital and physician group. Fair market value issues also need to be analyzed if the hospital is assuming the accrued paid time off from the physician group at no cost to the physician group.

-Tail Liability Insurance- Upon the purchase of a physician group practice by a hospital, the parties will want to ensure that there is no gap in liability insurance coverage for both the physician group entity and the underlying physicians. In many instances, the physicians can be added to the hospital liability policies at closing, with no gap in coverage and no tail insurance issues. If the physician practice purchase is structured as a purchase of assets, however, the liability insurance coverage for the physician practice group will typically terminate upon the sale to the hospital, and tail insurance coverage will be needed to cover the liability of the physician practice entity for claims made after the closing date (and after the practice group insurance policies have been terminated). The physician practice group will often request that the hospital pay for

such tail coverage for the transaction, since the tail coverage would not have been needed unless the transaction had occurred. Whether the hospital will agree to pay for such costs is a point of negotiation.

Physician Hospital Organizations

Purposes and Objectives of Physician Hospital Organizations (PHOs)

At the inception, PHOs were fundamentally a response to the leverage and reimbursement models being developed and aggressively pushed by third-party payer organizations. Although initially this was primarily a strategy of the large nonprofit health maintenance organizations (HMOs), even the traditional nonprofit third-party payors recognize the potential financial benefits of cost control through primary care capitation reimbursement mechanisms, global fees, and prior approval of procedures for cost control.

The response by the hospital and physician communities was essentially both proactive and protective, and to negotiate with third-party payers to deal effectively with new reimbursement models.

Most stakeholders in the healthcare industry recognized that (1) network agreements by hospitals and groups of individual physicians, or individual physicians, presented significant antitrust issues (in large part based on a series of antitrust investigations, consent decrees and settlements announced by antitrust enforcement agencies) and (2) for both protective and progressive reasons, development of PHOs represented an opportunity for “medical staff alignment” and related strategic benefits, such as:

- Development of hospital employment models;
- Clinical integration and continuous quality improvement (CQI) as a harbinger of P4P or accountable care organizations (ACOs);
- Development of clinical care pathways, treatment protocols, and standard credentialing criteria;
- Development of medical information systems—the harbinger to “mandatory” EHR;
- Development of risk pools, self-insurance products, purchasing organizations, and management organizations; and
- Creation of synergy, leverage, and strategic alignment

Organizational Structure Options for Healthcare Delivery

The organization structure options vary, depending essentially on the strategic scope of the venture and the reimbursement options.

- Models focusing more on medical staff alignment and clinical decision issues (such as protocol development, clinical integration and information development, electronic health records, etc.) do not present the antitrust risks associated with reimbursement strategies, and allow structures that are based more on agreements among the participating parties than the creation of a single entity or an integrated delivery system.
- Models focusing on third-party payment issues do present significant antitrust risks and the nature of those models would differ on a spectrum of complexity based upon whether the PHO was simply a conduit for negotiation and influence of fee for service third-party payer arrangements, which individual providers were free to accept or reject, versus reimbursement mechanisms that would trend toward the “greater integration” involving capitation, global payments, risk sharing, etc., all of

which have the antitrust issues mentioned above and explained subsequently in this Section.

The degree of legal, financial, and structural integration would be dependent on the third-party reimbursement strategies, with the degree of integration, which can be viewed as a journey toward an integrated delivery system, escalating with increased financial control and risk.

At the lowest level of complexity and integration would simply be agreements among individual entities, such as a hospital (or a hospital system) and physicians (or their group practices) to participate in the various PHO activities, i.e., network services, EHR, clinical integration, etc.

At the moderate level of complexity and integration would be the formation of a physician hospital organization (PHO) as a single legal entity owned and controlled by the hospital and an independent physician association (IPA). This entity, however, would still be an entity constructed by agreement among hospitals and allegedly competing physician practices, again raising the antitrust risks. As noted later, the antitrust enforcement agencies have issued integration guidelines for healthcare organizations.

The most integrated/most complex option is the integrated delivery system (IDS) in which all of the payor, hospital, and physician entities and functions are included, either as subsidiaries or by direct ownership or employment, within the IDS. Examples of IDS Structures would be Kaiser Permanente, Cleveland Clinic, and Geisinger Health System.

Operating Models

As you can see, the structure and degree of integration is dictated by the financial strategy, with the fundamental distinction being between non-risk bearing and risk bearing networks.

Non-Risk Bearing “Rental” Network

- Model services primarily as a contracting vehicle for otherwise independent providers;
- Integration or connectivity created only by contract—no integration or ownership or risk; and
- Lack of integration poses the most antitrust risk and contracts typically negotiated/administered using “black box” or “messenger” mechanisms

Risk Bearing Networks

-Organizational structure-

(1) Direct licensing and compliance with state regulatory, insurance, and capitalization requirements;

(2) Joint or contractual arrangement with insurance entity

-Product Design-

(1) Withholds;

(2) Capitalization;

(3) Financial and actuarial expertise for product design;

(4) Financial resources to accept risk.

Finally, the least inclusive and complex models for PHO or joint venture activities would be single service entities, such as independent diagnostic testing facilities (IDTF), imaging centers, ambulatory surgery centers (ASC) and laboratories, which are simply designed to participate with any and all third-party insurance programs. There would still be plenty of regulatory complexity regarding the Stark Law, the AKS, ownership, and nonprofit status, but this typically would not present the same level of antitrust risk as the other models.

Regulatory Issues

Applicability of Securities Laws

Generally, in order to avoid securities law related organizing costs, lawyers involved in establishment of PHOs and related IPAs have sought to structure the ownership interests (usually stock or LLC membership interests) so they would not be considered securities for purposes of the Securities Act³⁸ or applicable state blue sky law. The key characteristics of a security are: (1) its ability to participate in the earnings of the company that issues it; (2) the opportunity for the security to increase or decrease in value relative to the initial amount invested in exchange for the security; and (3) free transferability of the security.³⁹ Therefore, “stock” or “membership interests” issued by most PHOs and IPAs were structured to not receive dividends or distributions of PHO or IPA earnings and to require payment by the PHO or IPA to the owner of exactly the amount invested by that hospital or physician in exchange for the stock or membership interest. Further, PHO and IPA interests were issued subject to prohibitions on transfer to any third party without approval by the PHO or IPA governing board. Alternatively, a number of PHOs were organized as nonprofits that did not seek federal tax exemption. This is because nonprofit membership interests either (1) have state law restrictions on

³⁸ Securities Act of 1933, 15 U.S.C. § 77a et. seq.

³⁹ These characteristics follow from *Securities and Exchange Commission v. W. J. Howey Co.*, 328 U.S. 293, 298 (1946) definition of an investment contract under Section 2(l) of the Securities Act and subsequent interpretive case law.

distributions and liquidating distributions that prevent them from being a security or (2) are specifically excepted from federal registration requirements.⁴⁰

Antitrust Law and Federal Trade Commission/Department of Justice Guidance

Although most PHOs are organized by a single hospital or integrated hospital system, participation by competing physicians creates potentially serious antitrust issues under Section 1 of the Sherman Act.⁴¹ The two most common antitrust issues are: (1) the potential for horizontal price fixing agreements among physicians who participate in the PHO; and (2) exercise of physician market power through participation in the PHO.⁴²

Although there is little case law, the antitrust enforcement agencies have: (1) issued a number of advisory opinions related to specific network proposals;⁴³ (2) challenged a number of provider networks resulting in consent decrees;⁴⁴ and (3) published policy statements and guidelines,⁴⁵ which collectively provide substantial guidance to consider in advising PHOs how to minimize antitrust risk from their activities.

-Messenger Model for Non-Risk PHOs- A commonly used approach to antitrust compliance is the messenger model arrangement, which seeks to avoid creating an unlawful horizontal agreement among competitors on price and price related terms. Statement 9 of the enforcement agencies' *Statements of Antitrust Enforcement Policy on Health Care (Healthcare Statements)* provides guidance regarding how to conduct

⁴⁰ See Mo. Rev. Stat. § 355.661.1 and Mo. Rev. Stat. § 355.691.1(6); see also 15 U.S.C. § 77c(a)(4).

⁴¹ Volume 2, Health Care Antitrust Law, Section 15A-2, p. 15A-3-4 by John S. Miles, Clark Boardman Callaghan (1992-1995) as Supplemented through July 2009, Thompson Reuters, West, hereinafter referred to as "Miles"

⁴² Miles at 15A-4

⁴³ Miles at 15A-10. See advisory opinions cited in footnote 58.

⁴⁴ Miles at 15A-11, 13; see also Overview of Antitrust Actions in Health Care Services and Products, www.ftc.gov/bc/110120hcupdate.pdf.

⁴⁵ U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care, Statement 8, 9 (1996), available at www.ftc.gov/bc/healthcare/industryguide/policy/index.htm. Statement 8 addresses physician networks. Statement 9 addresses "multiprovider networks," including PHOs.

messenger model operations.⁴⁶ An advisory opinion issued by the FTC in 2003 also provides guidance on structuring a compliant messenger model.⁴⁷ Conversely, the North Texas Specialty Physician decision issued by the Fifth Circuit in 2008 provides examples of a “broken messenger” model.⁴⁸ Further, many of the consent decrees curtailed actions taken by “failed” messenger model provider networks that amounted to unlawful agreements among the competing network providers.⁴⁹

The basic messenger model requires the PHO to serve merely as a passive conduit for transmittal of offers, counter offers, and decisions between payers and individual PHO providers. This technique does not result in a horizontal price agreement among competing providers because each provider unilaterally decides what prices it will individually accept.

To become a more efficient conduit, many PHOs will periodically obtain from each PHO provider the minimum fees or fee ranges it will accept and compile these individual decisions into a document that predicts for the payer which PHO providers would accept offers from the payer at different fee levels.⁵⁰ This is sometimes referred to as the “standing offer” or “floor authority” of the PHO providers. It is important for antitrust compliance that the PHO transmit to its providers any offer that a payer wants to make that is less than the “standing offer” or “floor authority.”

Examples of mistakes made by provider networks in attempting to execute a messenger model include: (1) negotiating terms with a payer prior to transmitting the offer to PHO participants; (2) polling participants about acceptable fees and using those opinions to influence the payer’s offer; (3) refusing to messenger to PHO participants any offer

⁴⁶ Miles at 15A:14, p. 15A-108

⁴⁷ FTC Staff Advisory Opinion to Bay Area Preferred Physicians (Sep. 23, 2003), *available at* www.ftc.gov/bc/adops/bapp030923.shtml.

⁴⁸ *FTC v. North Texas Specialty Phys., Inc.*, 528 F.3d 346 (5th Cir. 2008).

⁴⁹ Miles at 15A-109, footnote 2

⁵⁰ Miles at 15A-116-117.

made by a payer; (4) requiring the PHO board to approve a payer's offer before it will be messengered to PHO participants; (5) using fee schedules, parameters, or guidelines to sway or influence a payer's offer; (6) encouraging or requiring PHO providers not to contract with payers except through the PHO; and (7) conditioning payer discussions with the PHO upon the payer meeting particular demands.⁵¹

The key to antitrust compliance for messenger model operations is to avoid any action that would create, facilitate, or result in an agreement among competing providers in the PHO on price terms or terms and conditions affecting price. It is not always obvious or clear to PHO executive directors when the line from permissible to impermissible conduct is crossed, so frequent consultation with antitrust counsel is strongly recommended.

-Financial Risk Sharing- The easiest route for a PHO to negotiate prices on behalf of its network providers is for the providers to share substantial financial risk for the services that all of them deliver. Even then, however, the group may not exercise market power.⁵²

(1) Substantial Financial Risk- Healthcare Statement 9 identifies five specific methods by which participants in a provider network may share substantial financial risk with respect to healthcare services they provide to patients of payers contracted through a provider network. These are:

- Capitation—A fixed per member per month payment for all services provided by network participants to members of a health plan.
- Percent of Premium—Payment to the PHO by the health plan of a percent of the premiums collected with respect to its health plan members in exchange for

⁵¹ Miles at 15A-125.

⁵² Miles at 15A-15A:5 and 15A:6

provision by PHO providers of all healthcare services needed by the health plan's members.

- Withholds—Withholding a percentage of payments made for services rendered by PHO providers and requiring achievement of utilization or cost reduction goals by the network providers to earn payments from the amounts withheld.
- Bonuses/Penalties—Payments to PHO providers or assessment of penalties upon PHO providers for achievement or failure to achieve agreed utilization or cost reduction targets.
- Global or All-Inclusive Rate—Payment to specified PHO providers of an agreed global or all-inclusive fee for the entire bundle of services required to treat a particular episode of care.⁵³

(2) Market Power—Exclusivity

Financial integration is not a “free pass” from the antitrust laws, but simply subjects the PHO or network to analysis under the rule of reason. Thus, even if participants in the PHO share substantial risk, the PHO may still run afoul of the antitrust laws if the PHO has or uses “market power,” that is, the power to raise prices above a competitive level. Factors to consider in such an analysis are market definition, competitive effects, and any efficiencies associated with the formation and operation of the network. The exclusivity of the network's contracting arrangements will also play a key role in the analysis: if the network has exclusive arrangements with a large percentage of physicians in the relevant market, it is more likely to draw antitrust scrutiny. In determining whether or not a multiprovider network is exclusive, the agencies look both at contract terms and at other factors to see if a network that is “nonexclusive” by its terms is in fact “exclusive.” Further, networks that are nonexclusive but have contractual mechanisms (e.g., higher reimbursement for physicians who do not join other networks) to incentivize providers to avoid or limit participation in other networks

⁵³ Health Care Statement 9.A.

are likely to be considered exclusive.⁵⁴ While there are no “safety zones” for multiprovider networks under the agencies’ Healthcare Statements,⁵⁵ financially integrated multiprovider networks can readily fit within the antitrust laws even without such presumptive protection where the demonstrable efficiencies from the network outweigh any anticompetitive effects of the network.

-Clinical Integration- Financial integration is not the only route to rule of reason analysis for a PHO, and is by no means mandatory to organize a PHO. Healthcare Statement 9 recognizes that substantial clinical integration “may produce efficiency benefits that justify joint pricing.”⁵⁶ For clinically integrated networks as for financially integrated networks outside of the safety zones (there are no safety zones for clinical integration), the touchstone of the analysis remains balancing likely anticompetitive effects through the exercise of market power against procompetitive efficiencies associated with the network. Thus, joint pricing agreements must be “ancillary” to the clinical arrangements, that is, reasonably necessary to further the goals of the clinical integration. Clinical integration is simply an alternate means of justifying joint pricing by providers through the creation of efficiencies; it cannot be a fig leaf for unrelated agreements on price.

There is no single format for clinical integration, nor is there a “checklist” that networks can follow to obtain clinical integration. The Healthcare Statements observe the heart of clinical integration is “an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.” Indicia of such a program may include: “(1) establishing mechanisms to

⁵⁴ See Health Care Statement 9.B.

⁵⁵ Health Care Statement 8 includes “safety zones” for financially integrated exclusive networks, based on the number of providers in the network and whether the network is exclusive (20% of providers in a market for exclusive networks, 30% for nonexclusive networks). But Statement 8 and its safety zones apply only to physician networks, they do not apply to multiprovider networks like PHOs. And even where Statement 8 does apply, its safety zones are not the sole means of organizing a network consistent with the antitrust laws: financially integrated physician networks with more than 30% of physicians in a market are still subject to the rule of reason, and as explained below, clinically integrated networks are subject to the rule of reason even without financial integration.

⁵⁶ Health Care Statement 9.A.

monitor and control utilization of healthcare services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.” The agencies have issued several advisory opinions providing greater detail within these general categories.⁵⁷ While these opinions primarily address physician networks, their guidance is relevant to PHOs, with the recognition by the agencies themselves that not all efficiencies available to physician networks may be available to multiprovider networks.⁵⁸

Stark Law and Anti-Kickback Statute Concerns

-Messenger Model- In the typical messenger model PHO, the only financial relationship among the participating physicians and hospitals is co-ownership of the PHO entity, which is not itself a provider nor generally a conduit for any payer payments to participating physicians or hospitals. No dollars flow either directly or indirectly between the participating hospitals and physicians so no financial relationship is created. One potential area of concern is in choosing which physicians are offered the opportunity to participate in the PHO. If physicians who have higher referral rates to the hospital are the only physicians allowed to participate in the PHO or are offered ownership on preferential terms, then the opportunity to participate may be considered an inducement intended to influence their continuing referrals to the hospital.⁵⁹ Accordingly, hospitals are advised to offer PHO participation to physicians based upon criteria not related to past or expected patient referrals to the hospital.

⁵⁷ Federal Trade Commission, *In re TriState Health Partners, Inc.* Advisory Opinion (April 13, 2009), available at www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf; Federal Trade Commission, *In re Greater Rochester Independent Practice Association* Advisory Opinion (Sep. 17, 2007), available at www.ftc.gov/bc/adops/gripa.pdf; Federal Trade Commission, *In re Follow-up to MedSouth Inc.* Advisory Opinion (June 18, 2007), available at www.ftc.gov/bc/adops/070618medsouth.pdf; Federal Trade Commission, *In re Suburban Health Organization Inc.* Advisory Opinion (March 28, 2006), available at www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf.

⁵⁸ Health Care Statement 9.A.

⁵⁹ Office of Inspector General, U.S. Department of Health and Human Services, Special Report on Joint Venture Arrangements (May 1, 1989); Office of Inspector General, U.S. Department of Health and Human Services, Special Fraud Alert; Joint Venture Arrangements (Aug. 1989) republished at 59 Fed. Reg. 65372 (Dec. 19, 1994).

Another area of concern is if the hospital and physicians share equally in governance of the PHO but the hospital funds greater than half of the PHO's needs for capital and operations. Such disproportionate funding could be viewed as an inducement for referrals in violation of the AKS or as a compensation arrangement with the physician co-owners for which there is no available Stark Law exception because the compensation (i.e., the disproportionate funding of the PHO) is not in return for any services or items provided by the physician co-owners of the PHO.

-Financial Risk Models- Provider-sponsored organizations (of which PHOs are one example) may be considered entities that furnish DHS if they employ a supplier or operate a facility that could accept Medicare reassignment with respect to the DHS provided by the supplier.⁶⁰ The Stark Law does contain a specific exception for risk sharing arrangements (including, but not limited to withholds, bonuses, and risk pools) between managed care organizations or independent practice associations and physicians for services provided either directly or through intermediaries to enrollees of health plans if the arrangement complies with the AKS and does not violate federal or state law or regulations governing billing or claims submission.⁶¹ There is a statutory exception to the AKS for risk sharing arrangements between health plans and providers.⁶² Through a safe harbor regulation, this exception has been expanded to include intermediary organizations such as a PHO, IPA, or similar organization as a link in the relationship between the health plan and the providers. The definitional provisions and the requirements to qualify a risk sharing arrangement for safe harbor protection are quite complex and may not fit the incentives that the health plan or PHO finds optimal from the perspective of controlling costs while maintaining or improving quality.⁶³ Accordingly, counsel will need to first determine if a proposed risk sharing arrangement can fit the safe harbor and, if not, then determine and advise the parties of

⁶⁰ 42 C.F.R. 411.351, Definition of Entity, subsection (2), 72 Fed. Reg. 51080-51081.

⁶¹ 42 C.F.R. 411.357(n).

⁶² 42 U.S.C. § 1320a-7b(b)(3).

⁶³ 42 C.F.R. § 1001.952(u).

the risk associated with being in an arrangement that does not fully meet the safe harbor.

HIPAA—PHO as a Business Associate

Whether or not a PHO will be considered a business associate for purposes of the HIPAA rules regarding privacy and security of personal health information will likely turn on whether or not the PHO will have access to such information. In a messenger model approach to operations, this is unlikely because the PHO merely facilitates direct contracts between health plans and the PHO's provider network. With PHOs that engage in either financial risk sharing or clinical integration, a PHO may need access to and use of personal health information in order to administer programs for utilization review, quality assurance, and medical management, and to make financial rewards or assess penalties associated with these programs. Accordingly, PHOs that engage in financial risk sharing and/or clinical integration models of operation will likely be business associates of either the providers in the PHO network or the payers with whom the PHO contracts or both.

Tax-Exempt Hospital Issues

For tax-exempt hospitals that participate in PHOs, the principal issue arises from either disproportionate funding of the PHO's capital and operating needs or the disproportionate allocation of financial risk to the hospital in the financial risk sharing mechanisms established through the PHO. In either of these situations, the PHO physicians benefit from the disproportionate burden undertaken by the hospital. This may cause the hospital to violate either the private inurement or the private benefit limitations within Section 501(c)(3) of the IRC, thus putting the hospital's federal tax exempt status at risk.

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