Hospital-Physician Relationships After National Health Reform: Moving From Competition To Collaboration

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INTRODUCTION

National health reform ("PPACA")2 has lent new urgency to the healthcare industry's transition to systems-based care management, and away from the recent "norm" in which hospitals have competed aggressively with the physicians practicing on their medical staffs for control of diagnostic and treatment services that can be performed outside of the traditional hospital setting.

It is generally acknowledged that the "competitive" care model has produced fragmented care linked to lower quality and increased cost, and has exacerbated existing tensions between hospitals and the physicians practicing in their communities. PPACA attempts to overcome this fragmentation through a variety of innovative mechanisms. The one that has generated the most industry interest is the Accountable Care Organization, or ACO, as a vehicle for hospital-physician collaboration.3 Conceptually, ACOs are groups of providers (such as hospitals, physicians and other outpatient and post-acute providers) who align themselves to provide coordinated service across a continuum of care, and position themselves to contract jointly with CMS for incentive-based payment structures linked to quality of care.4

Under the current regulatory framework, substantial fraud-and-abuse and antitrust hurdles must be overcome before hospitals and physicians can create the level of

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1. This article is adapted from an article co-authored with Deborah A. Datte, Esquire, When Your Physicians Are Your Competition: What's a Hospital to Do?, PENNSYLVANIA BAR INSTITUTE (Oct. 2010).


4. Id.
financial and clinical integration required for effective ACOs. The industry is awaiting promised guidance from the regulatory agencies—Center for Medicare and Medicaid Services (CMS), the Office of Inspector General (OIG), the Department of Justice (DOJ) and Federal Trade Commission (FTC)—as to waiver criteria that will enable health systems to move forward without running afoul of these laws. In the meantime, hospitals need to develop more immediate vehicles for working effectively with their medical staff physicians that will enable them to align both financially and clinically, in a way that is mutually beneficial and yet does not run afoul of the fraud and abuse and antitrust laws. This article suggests and discusses some new approaches that offer immediate opportunities for enhanced hospital-physician collaboration.

Aligning hospital and physician incentives is one of the first steps towards a coordinated care model that consistently produces high quality, efficient services.

TODAY’S COMPETITIVE HEALTHCARE LANDSCAPE

One of the most prominent critics of the current fragmented and incentive-driven healthcare system is Harvard surgeon Atul Gawande, M.D., who has declared that we are witnessing a “battle for the soul of American medicine.” Dr. Gawande is highly critical of the competitive model of healthcare delivery, noting that the financial incentives embedded in our current healthcare system contribute to poorer outcomes while driving up cost. Among other things, physician ownership of advance technologies, diagnostics and surgery centers has led to over-utilization, higher complication rates, and escalating charges. Aligning hospital and physician incentives is one of the first steps that must be considered by hospitals and health care systems interested in moving towards an integrated and coordinated care model that consistently produces high quality, efficient services.

One of the drivers for integration is financial. Over the last two decades, physician competition has had a serious negative impact on hospitals’ revenue base. Outpatient diagnostic centers, ASCs, and specialty hospitals have seriously eroded hospitals’ bottom line, particularly in the more lucrative service lines such as cardiology, orthopedics and surgery. As of 2006, the AHA reported that 37% of all outpatient surgeries in the United States were being performed at ASCs. The newest economic threat is the rise of the medical tourist industry, in which foreign hospitals provide cardiac surgery and other advanced treatment at a fraction of the cost of American hospitals.


7. Id.


In addition to the financial considerations, increasing numbers of studies are demonstrating that coordination of care is a critically important factor in improving quality and safety and reducing the overall cost of healthcare. The Mayo Clinic, one of the country’s acknowledged quality leaders, has put its physicians on salary so as to remove any personal incentives to practice in a particular way, and so that it can implement standardized evidence-based practice protocols throughout the system.\(^\text{11}\) Other quality leaders, such as Geisinger Health System, the Veterans Administration and the Cleveland Clinic, likewise have found that the elimination of individual financial incentives is one critical factor in moving towards high quality and cost effective health care delivery.\(^\text{12}\) Foreign competitors are also able to produce high quality, low cost hospital services through, among other things, physician employment and standardization of technique.\(^\text{13}\) All of these systems, after removing the personal financial incentives, have found it easier to develop and implement coordinated care models that lead to materially higher quality and more efficient care.

In fact, the “patient protection” components of PPACA are all based on the core premise that in order to improve quality and reduce cost, the healthcare industry must shift towards a systems-based, coordinated approach to the delivery of healthcare services. PPACA seeks to move the industry in this direction through a variety of specific measures including:

- Encouraging the development of integrated models such as ACOs and health homes through a variety of demonstration projects\(^\text{14}\);
- Promoting bundled payment models, value-based purchasing and shared savings programs as a way of moving providers to more coordinated care systems\(^\text{15}\);
- Promoting the development and use of effective electronic health records systems within communities of providers in order to enhance care coordination.\(^\text{16}\)

The challenge for a community health system is to develop a model for coordinated care that reduces or eliminates the negative impact of physician competition and replaces it with a clinically integrated system. Many community healthcare systems are not in a position to adopt a fully integrated model such as the Mayo Clinics and Geisingers have done. And until the government issues further concrete guidance on the ACO model, health systems will likely not opt to make the substantial commitment of time and resources necessary to develop an ACO.

In this article, we discuss some new models that can help community health systems take the first steps towards more rational, clinically integrated systems of care,

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11. Swensen et al., *supra* note 8, at 429.


14. *Id.* §2703(a) (amending Title XIX of the Social Security Act, 42 U.S.C. §1396a et seq., by adding at the end new Section 1945).

15. *Id.* §§3001(a) & 10335 (amending §1886 of the Social Security Act, 42 U.S.C.§1395ww); §§3022 & 10307.

16. *Id.*
consistent with the current mandates of the federal fraud and abuse and antitrust laws.

**FRAUD AND ABUSE BARRIERS TO COLLABORATION**

Before developing models for clinical integration, it is important to examine, first, how the current federal regulatory framework has helped drive hospitals and physicians apart. One of the significant unintended consequences of the Anti-Kickback Statute (AKS)\(^{17}\) and the Ethics in Patient Referrals Statute (Stark)\(^{18}\) over the last twenty years is that they have severely limited hospitals and physicians' ability to partner with each other—thereby driving them to compete in a variety of settings in which they would have been more likely to collaborate in the pre-AKS era.\(^{19}\)

In fact, it is striking that, although both AKS and Stark were enacted to curb potential physician referral abuses, the reality is that both sets of regulatory schemes (consisting of statutes, regulations, extensive commentary and case law interpretation), have actually encouraged more physician-only ventures, and have reduced the opportunities for hospitals to partner with physicians.\(^{20}\) The Office of Inspector General of the Department of Health and Human Services (“OIG”) has taken a particularly dim view of hospital-physician joint ventures dating back to its original Special Fraud Alert issued more than two decades ago, in 1989.\(^{21}\) At that time, the OIG noted that hospital joint ventures with physicians could be intended not so much to raise investment capital legitimately to start-a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for referrals, thus leading potentially to over-utilization and increased program expenditures. The Fraud Alert identifies a variety of concerns with joint venture relationships, including the potential over-utilization of services, increased costs for federal health care programs, corruption of professional judgment, and unfair competition. The OIG has reiterated these concerns many times in regulatory guidance and Advisory Opinions.\(^{22}\)

**Ambulatory Surgery Centers**

The ASC safe harbors provide a particularly clear example of how the federal fraud-and-abuse have created a competitive environment which motivates physicians to move away from hospitals and invest on their own or with other physicians to compete creating outpatient centers. The OIG's commentary emphasizes that the ASC safe harbor was developed specifically to encourage physician investment in ASCs as a way of promoting greater development and use of ASCs as a low-cost alternative to hospital inpatient and outpatient surgery.\(^{23}\) The same commentary

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17. The Anti-Kickback Statute (AKS), 42 U.S.C. §1320a-7b(b), prohibits the knowing and willful offering, payment, solicitation or receipt of any form of remuneration as an incentive to refer a patient for Medicare-reimbursable items or services.

18. The Ethics in Patient Referrals Act (Stark Law), 42 U.S.C. §1395nn, prohibits a physician who has a direct or indirect financial interest in an entity (or whose family member has such an interest) from referring to that entity for Designated Health Services (DHS) unless the relationship is structured to meet Stark's requirements. It also prohibits the entity providing DHS from billing Medicare for any DHS provided pursuant to that prohibited referral.

19. Although few would argue that the AKS has not played an important and salutary role in combating "true" healthcare fraud and abuse over the past two decades, it can likewise not seriously be questioned that both the AKS and the Stark laws have created very substantial and costly impediments to forming and maintaining legitimate and socially desirable business relationships between and among various types of health care providers.


23. Dep't of Health & Human Servs., Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor
strikes a cautionary note with regard to hospital involvement in such ventures.\textsuperscript{24} Physician-investors who develop ASCs are given more favorable treatment based on the presumption that ASCs (whether office-based or freestanding) pose the least risk of fraud and abuse when they are operated essentially as an extension of a physician's private practice.\textsuperscript{25}

The regulatory hurdles for physician-owned ASCs are relatively straightforward to overcome, particularly since ASCs are largely excluded from regulation under the Stark Law,\textsuperscript{26} and therefore, from a federal fraud and abuse perspective, only the AKS ASC safe harbor requirements must be met.\textsuperscript{27} The OIG has established four distinct safe-harbors for physician-owned ASCs, only one of which permits an ownership share to be held by a hospital. The first three are surgeon only, single-specialty, and multi-specialty ASCs, all of which involve only physicians. The fourth exception is for the hospital-physician ASCs.\textsuperscript{28} Not only does the hospital-physician ASC safe harbor have more requirements than any of the physician-only safe harbors, it entails significantly more regulatory risk because those requirements, as interpreted and applied by the OIG, are technically impossible to meet.

The threshold requirement for all ASCs is that they must be certified by the Centers for Medicare and Medicaid Services (CMS) as operating exclusively for the provision of surgical services for patients not requiring hospitalization and whose expected stay in the ASC does not exceed 24 hours, and meeting all of CMS's regulatory requirements for ASC.\textsuperscript{29} All four of the ASC safe harbors permit investment by "passive investors," i.e., those who are not employed by the ASC or any ASC investor, not in a position to provide items or services to the ASC, or to make or influence referrals to the ASC or to any of its investors, directly or indirectly.\textsuperscript{30}

All four ASC safe harbors share a variety of standard prohibitions—against loans to investors, investment terms based on volume or value of referrals, unbundled ancillary services, and discrimination against Federal health care program beneficiaries—which can be complied with through a properly structured arrangement.\textsuperscript{31} The additional requirements for the physician-only ASCs actually encourage use of and referral to the ASC, because they are designed to ensure that the physician-only ASCs operate essentially as extensions of the physician's private practice activities.\textsuperscript{32} The multi-specialty ASC is the most restrictive of the physician-only safe harbors because of the OIG's concern that physicians practicing within different specialties could derive an improper financial incentive to refer to each other for procedures they cannot personally perform, thus potentially leading to over-utilization and driving up Medicare costs.\textsuperscript{33} However, as with the other physician-only

\textsuperscript{24} Id.
\textsuperscript{25} Id.
\textsuperscript{26} See 42 U.S.C. §1395nn(h)(6) (ASC services not included within the definition of Designated Health Services (DHS) that are subject to the Stark proscriptions). Note, however, that to the extent that an ASC is a supplier of DHS, such as durable medical equipment (DME), a physician-investor's referral to the ASC could be subject to the Stark prohibition for procedures requiring the use of such DME.
\textsuperscript{27} The AKS ASC safe harbor is at 42 C.F.R. §1001.952(r). Note that most states have analogous fraud and abuse laws pertaining to the Medicaid program. However, most such laws largely track the federal fraud and abuse laws and, in any event, are beyond the scope of this article.
\textsuperscript{28} Id. §1001.952(r)(1)-(4).
\textsuperscript{29} Id. §1001.952(r); 42 C.F.R. §416.2 (Definition of ASC); AKS Final Rule, supra note 23, at 63,535.
\textsuperscript{30} Id.; AKS Final Rule, supra note 23, at 63,535.
\textsuperscript{31} 42 C.F.R. §§1001.952(r)(1) (surgeon only); 1001.952(r)(2) (single specialty); 1001.952(r)(3) (multi-specialty).
\textsuperscript{32} AKS Final Rule, supra note 23, at 63,536. The OIG explains: "In such cases, medical decision-making may be corrupted by financial incentives offered to potential referral sources who stand to profit from services provided by another physician. Id. See also OIG Advisory Opinion No. 03-5, at 5 (Feb. 6, 2003), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/2003/a0305.pdf (noting that in the case of an ASC owned in part by a large multi-specialty practice, there is a substantial likelihood of cross-specialty referrals for services performed in the ASC).
ASC safe harbors, the OIG has less concern regarding the potential for over-utilization by physician-investors referring patients for procedures they personally perform. Thus, these physician-only ASC safe harbors make it relatively easy for physicians to invest in and refer to ASC, with or without financial partners such as for-profit ASC management companies, so long as they follow certain well-accepted parameters.

The hospital/physician ASC safe harbor is significantly more problematic because, as noted above, a hospital/physician ASC cannot be made to fit squarely within the hospital/physician safe harbor. As a consequence, hospitals seeking to joint venture with their physicians for investment in ASCs generally must impose a variety of additional safeguards as an AKS risk management strategy. However, those additional safeguards often prove unpalatable to physicians, making physicians generally less favorably disposed towards joint venturing with hospitals than with other physicians or passive for-profit partners, who are not subject to the same restrictions.

The problematic requirement for hospital/physician ASCs is that the hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity. The OIG has explicitly stated that hospitals are generally in a position to make or influence referrals by virtue of their relationships with employed physicians, administrative personnel, or even physicians who are simply on their medical staffs. The OIG commentary states:

[We] believe that hospitals ... may be referral sources in some circumstances. By way of example only, a hospital may be in a position to influence referrals when it employs physicians who make referrals, when it owns surgical practices, or when it is affiliated with a "friendly" or "captive" professional corporation owned or controlled by its employees. We further believe that some employees, such as certain marketing and administrative staff, may be referral sources.

The OIG has reinforced this position in its advisory opinions regarding hospital-physician joint ventures, which invariably note that the hospital is unable to meet the safe harbor requirement that it not be in a position to make or influence referrals directly or indirectly to any investor or the ASC. Through a series of Advisory Opinions, the OIG has identified and sanctioned a specific set of safeguards as sufficient to overcome its concern that the hospital will act as a referral source for the ASC. Typical safeguards are:

- Hospital employees will not refer patients to the ASC;
- The hospital will refrain from any actions to require or encourage any members of its medical staff to refer patients to the ASC or to the physician-investors;
- The hospital will not track referrals, if any, by its medical staff to the ASC or to the physician-investors;
- Any compensation the hospital pays its medical staff will be at fair market value and will not take into account any referrals to the ASC or to its physician-investors;
- The hospital will inform its medical staff annually of these measures.

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34. 42 C.F.R. §1001.952(r)(4).
35. AKS Final Rule, supra note 23, at 63,537.
37. See, e.g., OIG Advisory Opinion No. 09-09, supra note 36, at 5-6; OIG Advisory Opinion No. 08-08, supra note 36, at 7; OIG Advisory Opinion No. 07-05, supra note 36, at 3-4; OIG Advisory Opinion No. 01-21, supra note 36, at 10; OIG Advisory Opinion No. 01-17, supra 36, at 3-4.
In some cases, the hospital also agrees that it will continue to operate its own (com-
peting) outpatient surgery facility. These measures, although logically related to
the OIG's expressed AKS-related concerns, are often hard "sells" to potential phy-
sician investors. From the physicians' vantage point, it seems counter-productive to
invest with a partner that must certify that it will take steps not to generate business
for the venture, and in some cases, will even continue to operate its own competing
service. All too often, the "real world" physician response is to reject the hospital's
offer to joint venture, and instead, seek investors that do not operate subject to the
hospital's regulatory constraints.

**Advanced Diagnostics**

Under the AKS and Stark, physicians have substantial latitude to invest in and
provide advanced diagnostic services in the context of their own, private office-
based practices. Both Stark and the AKS permit physicians to invest in and offer ad-
vanced technologies through their office-based practices, so long as they comport
with basic regulatory requirements for the provision of ancillary services. With the
proliferation of very large multi-speciality practices, with substantial financial re-
sources and access to capital, lucrative ancillary services are increasingly being
pushed out into multiple competing sites throughout the community. As Gawande
pointed out rather provocatively in *The Cost Conundrum*:

> [T]here are the physicians who see their practice primarily as a revenue stream.
> . . . They take a Doppler ultrasound course, buy a machine, and start doing their
> patients' scans themselves, so that the insurance payments go to them rather than
> the hospital.39

Stark's ancillary services exception permits physicians who qualify as a group
practice as defined in the Stark statute to provide advanced technological services
subject to certain requirements designed to ensure that the service is truly "ancillary"
to a *bona fide* office-based practice, and are billed as such.40 The AKS essentially piggy-
backs on the Stark Law's in-office ancillary services exception, in its safe harbor for
Investments in Group Practices, which permits physicians to practice through indi-
vidual and group practices to the same extent as permitted under Stark.41

By contrast, the opportunities for hospitals and physicians to collaborate to pro-
vide advanced diagnostics are severely constricted. Stark restricts the ability of
physicians to invest in and refer to freestanding diagnostic entities, which in turn
makes it difficult for hospitals to joint venture with them in those areas. Stark has
no exception that permits physician investment in freestanding centers by physi-
cians who are in a position to refer to those centers.42 For that narrow category of
cases falling outside the Stark prohibition, then the investors must still comply with
the AKS small investment safe harbor that (i) no more than 40% of each class of in-
vestors be held by, and (ii) no more than 40% of the gross revenues be generated by,
investors who are "in a position to make or influence referrals" to the center.43 As in
the case of the AKS safe harbor, the OIG has made it clear that it considers hospi-
tals as having the ability to make or influence referrals.44 Therefore, technically, a
hospital may not hold more than a 40% ownership share in a joint venture with physicians
(who themselves cannot be in a position to refer) under the small investments

38. See, e.g., OIG Advisory Opinion No. 09-09, *supra* note 36, at 6.
41. 42 C.F.R. §1001.952(p).
42. See discussion regarding Stark, *supra* note 18.
43. 42 C.F.R. §1001.952(a)(2)(i) and (vi).
44. AKS Final Rule, *supra* note 23, at 63,524 ("[C]ertain investors that are arguably not "licensed pro-
    fessionals" such as hospitals . . . may be in a position to generate business for an entity in which they have
    an investment interest and to receive distributions that may be remuneration for that business.")
safe harbor. For not-for-profit hospitals, relinquishing that degree of control over a joint venture with physicians could run afoul of the tax laws which generally require the not-for-profit to retain a majority interest.

This was the situation that the OIG reviewed in OIG Advisory Opinion No. 03-12 (May 22, 2003)—which involved a joint venture between a hospital (51% shareholder interest) and a group of radiologists (49% shareholder interest) to develop an MRI center. The OIG noted that the arrangement fell outside the Small Entity Investment safe harbor based on the hospital’s 51% ownership share. In order to secure OIG approval of the arrangement, therefore, the hospital certified that it would take several steps to limit its ability to make or influence referrals (similar to those discussed above with regard to ASC joint ventures). Specifically, the hospital certified it would:

- Refrain from taking any action to require or encourage affiliated physicians to refer patients to the facility;
- Not track referrals made by affiliated physicians to the facility;
- Ensure that any compensation paid to affiliated physicians under employment or personal services contracts would not be related directly or indirectly to the volume or value of the referrals or other business generated for the facility; and
- Notify its affiliated physicians of these measures on an annual basis.\(^45\)

Even with such measures in place, the OIG’s approval of the joint venture was not a foregone conclusion. The OIG explained that its decision not to impose administrative sanctions was also based on the following additional factors:

- That the other physician investors were radiologists, and therefore not generally in a position to make or influence referrals\(^46\);
- That the hospital certified that it would continue to operate its own inpatient and outpatient radiology department and that only a small percentage (less than 10%) of the MRI facility’s business would actually come from the hospital or its employed physicians;
- That any return on investment to the parties was proportional to their ownership shares; and
- That the series of proposed ancillary agreements did not appreciably increase the risk of fraud and abuse.

In addition, the OIG in that case made particular note of the fact that the proposed open MRI would be the only one available in the hospital’s three-county service area. If the radiologists in the case just described, had opted to secure their own financing or to joint venture with a for-profit management company, they could more easily have fit their enterprise into the Small Entity Investment Safe Harbor, and possibly avoided any need to seek an Advisory Opinion from the OIG. The presence of the hospital complicated the venture from a regulatory perspective, and placed it at higher risk of regulatory sanction. All too often, given the business options available to them, physicians have simply chosen to avoid entering into these types of ventures with their local hospitals.

Hospital-physician collaboration was also made more challenging as a result of Stark’s revised “under arrangements” regulations that took effect October 1, 2009. Whereas before October, 2009, hospitals and physician groups were able to collaborate in the provision of such services as cardiac catheterization services through contractual joint venture relationships in which physician groups both refer patients and provide the professional and technical components on the hospitals’ behalf, and the hospitals billed these services as hospital outpatient services (thereby avoiding


\(^{46}\) Although the OIG recognized that there are some instances in which radiologists may influence referrals by recommending follow-up treatment to the patient's attending physician, the OIG did not consider that potential to be significant in terms of the AKS analysis. Id. at 6-7.
Stark prohibitions against a physician-owned entity billing for self-referred services, CMS eliminated those arrangements with a change in regulatory interpretation pursuant to which physician owners are now included within the definition of the billing entity even when it is the hospital actually submitting the billing. The revisions to the “under arrangements” regulations have driven a further wedge between hospitals and physicians by making it more difficult for them to collaborate in the provision of advanced diagnostics and specialty services.

Specialty Hospitals

Community health systems have also, in the last decade, faced increasing competition from physician-owned specialty hospitals, which have proliferated notwithstanding regulatory obstacles posed by Stark and AKS, particularly with regard to the controversial Stark “whole hospital” exception. Although PPACA has finally closed the door to new development of physician-owned Specialty Hospitals, there are many existing hospitals that will continue to lawfully operate under the current statutory framework.

According to estimates based on statistics compiled by the American Hospital Association (“AHA”) in 2007, the number of specialty hospitals in the nation nearly quadrupled from 68 in 2000 to a projected 262 in 2008. They have been perceived as particularly threatening to community hospitals by virtue of their ability to siphon off the most lucrative services lines such as cardiology, orthopedics and general surgery, with which community hospitals have historically subsidized their unprofitable but vital services to the community such as emergency medicine, trauma, obstetrics, and “safety net” care of the uninsured.

The Stark Law’s “whole hospital” exception, which has had a checkered history and has now been eliminated on a going-forward basis by PPACA, provided a specific statutory carve-out for specialty hospitals. While the Stark Law’s “whole hospital” exception encouraged physicians to invest in hospitals, the AKS “small entity safe harbor” has made it difficult for hospitals and physicians to joint venture, for the reasons discussed above, with the net effect that physician-owned for-profit...
specialty hospitals have proliferated to the detriment of general service acute-care community hospitals.

In summary, over the last two decades, the fraud and abuse laws have encouraged physician competition and discouraged hospital-physician collaboration as more and more services traditionally found only in a full service hospital have progressively migrated out into the community, fueled by physician investment.

**ANTITRUST BARRIERS TO COLLABORATION**

The federal antitrust laws also stand as a major hurdle to effective hospital-physician collaboration. The federal government is highly skeptical of any form of horizontal or vertical integration between otherwise distinct healthcare entities. The concern is that such arrangements will facilitate joint contracting and "price-fixing," thereby further driving up the cost of healthcare services.

The classic example of this is the Physician-Hospital Organization (PHO) of the 1990s, a forerunner of the present-day ACO. PHOs were formed by hospitals and groups of physicians who generally had formed Independent Practice Associations (IPAs), joining together for the purpose of engaging in global risk contracting with managed care organizations. The underlying premise of the PHO was that the hospital and physician partners in the PHO were going to work together to "manage" the provision of inpatient and outpatient services to a defined patient population, and that the capitated payment structure would bring together the clinical expertise and financial risk, directly rewarding the providers for delivering efficient, cost-effective quality care.

A skeptical Federal Trade Commission (FTC) and Department of Justice (DOJ) generally regarded PHOs as thinly veiled attempts to gain monopoly leverage with the payors by bringing together the entire provider community to engage in joint contracting. Joint contracting could not only create market power and leverage with the payors but also create an opportunity to share financial data that could facilitate price fixing even outside the context of the PHO. In order to avoid FTC sanction, therefore, PHOs were forced to engage in "messenger model" contracting—a cumbersome structure in which the PHO (or an outside contractor engaged by the PHO) would act as a contracting agent on behalf of each of the component parts of the PHO separately and without sharing financial data with each other.

PHOs were also built on the premise that if hospitals and physicians joined together to form this new entity, they could access or create the tools necessary to effectively manage care so as to produce efficient, cost-effective quality care. However, in the 1990s, the healthcare industry in general had neither the technology nor the clinical infrastructure necessary to effectively manage care across a continuum of providers. The concepts of clinical protocols and evidence-based medicine were in their infancy, and community-wide intra-operable electronic medical records systems were largely non-existent. With few exceptions, therefore, PHOs found themselves incapable of effectively managing the care so as to either justify joint contracting from the FTC's perspective or to make a reasonable profit on the global capitated risk contracts that they did negotiate.

The FTC's first question, therefore, as it begins to examine how ACOs and other collaborative care models will pass muster under the antitrust laws is how much clinical integration is necessary to justify joint contracting. The FTC has said that "[i]n particular [it] will address the indicia of clinical integration sufficient to indicate that an ACO is likely to enable participating providers to improve quality of their health care services and whether joint price negotiation is reasonably necessary to achieve these efficiencies. Such indicia could include, for example, the degree to which the

53. This is precisely the question that was posed at the October 5, 2010 joint workshop on ACOs. See supra note 5.
providers engage in integrated activities, the information processes used to ensure that providers are coordinating patient care, incentives for providers to adhere to evidence-based care protocols such as financial risk sharing, and/or financial and resource investments made by providers."54 Effective clinical integration in this context thus becomes not only a business necessity but a legal mandate under the antitrust laws.

The FTC and DOJ are in the process of developing regulatory guidance on waiver criteria for ACOs, as mandated by PPACA. However, The New York Times recently reported a split between the FTC and the DOJ with regard to how aggressive the agencies will apply antitrust principles to these new vehicles for hospital-physician collaboration.55 Specifically, the Times reports that whereas the DOJ is urging a more relaxed approach, J. Thomas Rosch, an influential member of the Federal Trade Commission has argued to CMS and President Obama that without "vigorous antitrust enforcement," the new alliances of health care providers could reduce competition and increase costs to consumers.56 This internal debate "creates uncertainty about antitrust enforcement policy at a moment when scores of hospitals, clinics and doctor groups are eager to band together and test innovative ways of delivering care."57

The regulatory challenges posed by the fraud-and-abuse and antitrust laws, coupled with the business and clinical challenges of managing care across a continuum of affiliated entities, has proved daunting. However, the environment created by PPACA is fertile for the development of new and innovative approaches to collaborative care.

**NEW PATHWAYS TO HOSPITAL-PHYSICIAN INTEGRATION**

PPACA signals a new era in which integration, collaboration and coordination of care are seen as essential tools for controlling the spiraling costs of healthcare while maintaining and improving quality. However, PPACA itself does not resolve either the business challenges or the federal regulatory hurdles to hospital-physician collaboration, but rather encourages the industry to come up with solutions through trial and error.58 While the industry awaits further regulatory guidance on the development of the ACO model, healthcare entities need to be examining other, more immediate steps that they can take to move themselves further in the direction of clinical and financial integration.

In the healthcare industry today, the only "proven" model for achieving a successful, clinically integrated healthcare delivery system is the physician employment model, an approach that is neither achievable nor desirable for the vast majority of community health care systems in the country. In this article, we will briefly examine why the employment model has proven to be successful, and then discuss two other pre-ACO models that we believe offer potential paths for community health systems to develop more collaborative relationships with physicians that admit to their hospitals.

**Employment**

Full physician employment has been adopted by such quality leaders as Mayo Clinic, Geisinger and Cleveland Clinic, as a way of achieving clinical integration and

54. Id.
56. Id.
57. Id.
58. PPACA includes very substantial funding for a range of demonstration projects through which it is hoped that new viable solutions will emerge that can then be adapted and applied on a larger scale. See, e.g., Pub. L. No. 111-148, §2703(a) (authorizing up to $25 million to be awarded to the states for the Medicaid waiver program for chronic disease management).
eliminating individual physician financial incentives that can lead to fragmented care. The fraud and abuse laws offer substantial latitude for health systems that enter into *bona fide* employment relationships with physicians. Employment is regarded as less suspect from a fraud and abuse perspective because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them.

Employment is one of the AKS’s *few statutory* exceptions. The AKS specifically exempts “any amount paid by an employer to an employee (who has a *bona fide* employment relationship with such employer) for employment in the provision of covered items or services.” This exception is amplified by an employment “safe harbor” promulgated by the OIG, which clarifies that the existence of a *bona fide* employment relationship is determined by using the standards developed by the Internal Revenue Service (IRS) for distinguishing between employment and independent contractor relationships.

The Stark Law is only slightly more prescriptive than the AKS in delineating its employment exception. Stark carves out of its prohibitions any *bona fide* employment relationship so long as:

1. The employment is for identifiable services;
2. The amount of the remuneration under the employment is consistent with fair market value and not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the employed physician; and
3. The employment agreement would be commercially reasonable even in the absence of any referrals.

Integrated systems such as Mayo and Geisinger use the employment-model exceptions to attract high quality physicians with highly competitive compensation packages, but without the added financial incentives created by personal investment in diagnostic or surgical facilities. With the incentives removed, these health systems are able to secure greater physician buy-in to a comprehensive, coordinated care model, and thereby can much more readily achieve their business and their quality objectives.

**Clinical Network Model**

Community health systems that depend at least in part on non-employed, affiliated physicians for their physician services must seek out other ways of achieving both clinical and financial integration in the pre-ACO era. The first model we will discuss is the “clinical network model” in which a hospital contracts with both employed and non-employed physicians to form a clinical network whose purpose is (i) to provide coordinated inpatient and outpatient care service to meet a patient’s full continuum of patient care needs in a manner that will both increase quality and reduce cost across the spectrum of care, and (ii) to provide a mechanism for payor contracting that includes significant quality/safety incentives.

A contractual “clinical network” is a pre-cursor to an ACO. In a health care system that consists of a hospital and employed primary care physicians (“PCPs”), the health system may be in a position to develop a broader network through contractual relationships (“network contracts”) with non-employed specialty care physi-

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61. 42 C.F.R. §411.357(c). The Stark exception permits the payment of a productivity bonus based on services personally performed by the physician.
cians to provide coordinated care for the hospital's patients who are referred to them for care ("network patients"). The network contracts would create cross-referral relationships between the hospital, the employed PCPs and the non-employed specialists, and would also require a commitment by the participating specialists to meet certain network-wide quality criteria and evidence-based protocols. It could also help facilitate the implementation of a network-wide electronic medical records system that would promote the efficient exchange of medical information. The objective would be to help build the type of clinical integration that would ultimately enable the network to engage in quality-based incentive contracting with commercial or governmental payors covering the network patient population.

Obviously, such a proposal would require careful vetting under AKS and Stark, as well as the federal antitrust laws. Under AKS, the question is whether the cross-referral arrangement embodied by the network agreements constitutes "remuneration" and, if so, whether the arrangement fits within the cross-referral safe harbor.

The elements of the cross-referral safe harbor are as follows:

1. The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.
2. The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.
3. The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.
4. Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.

Although the OIG's commentary regarding this safe harbor is all directed to physician-to-physician referral, the regulations explicitly permit physician-entity referrals, and that appears to encompass referral relationships between and among physicians and hospitals. Even if the OIG were to determine (i) that the cross-referral arrangement involves remuneration and (ii) that the arrangement does not fit squarely within the safe harbor, there are safeguards that could be created to neutralize any attendant fraud and abuse risk.

In addition to the OIG analysis, one must also evaluate the proposed arrangement in light of the potential Stark exposure. It is even less clear whether CMS would analyze a cross-referral relationship as a "compensation" relationship under Stark, given that, unlike the OIG, CMS has never treated the opportunity to generate a referral as creating a "compensation" relationship for purposes of Stark analysis. Regardless, CMS's special rules on compensation, set forth at 42 C.F.R. §411.354 (d)(4), do expressly allow a referral requirement to be negotiated as part of a Stark-compliant agreement under the personal services exception or the fair market value exception or other applicable exception.

With regard to both the AKS and Stark, since the proposed contractual clinical network concept is charting new territory, this approach is well suited to the Advisory Opinion process to obtain agency clarification as to how they would apply their regulatory requirements to this type of arrangement.

The contractual clinical network model, which is designed to create a foundation for clinical integration within the network, avoids the antitrust pitfalls that have

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62. 42 CFR §1001.952(s).
63. Id. §411.357(d).
64. Id. §411.357(l).
plagued some other attempts at network contracting, based on the following broad principles:

- the parties are not engaged in joint contracting with regard to their basic services, but only with regard to the distribution of quality-based incentive payments to the health system generated by virtue of increased quality and efficiency of services provided to the patient population.
- the parties need not have access to each other’s financial data in order to implement the program—all that is needed is the quality data necessary to evaluate each participant’s performance against the agreed-upon quality benchmarks.
- the program not only achieves significant clinical integration but is designed for that very purpose; as such, it has substantial pro-competitive benefits that, we suggest, outweigh any identifiable anti-competitive impact.

The physician network model thus offers a potential vehicle by which community health systems can work with their non-employed, affiliated physicians to begin to build a coordinated care system without making the major financial and operational investment that would be required to adopt a full employment model or an ACO.

**Co-Management Services Agreement**

Co-management offers a different model for hospital-physician collaboration to achieve significant quality/safety goals along the full continuum of inpatient and outpatient services. Co-management is premised on the assumption that fully engaged physicians are in the best position to make quantum leaps forward in quality and safety both in the inpatient and outpatient settings. Physicians:

- provide the professional services and lead the inpatient and outpatient teams;
- have specialized clinical training and substantial hands-on experience;
- are in a position to know the patients and the caregivers personally both within and outside the hospital, and therefore have direct knowledge of the full continuum of care;
- are influential with and respected by other physicians.

Under the traditional model of healthcare delivery, physicians have had input into quality and safety in a largely ad hoc manner. Physicians serve in a variety of leadership positions related to quality/safety of services, often (at least in the past) on a volunteer basis. These positions include:

- Elected officers of the Medical Staff;
- Department chairs and division chiefs;
- Medical Executive Committee and Credentials Committee;
- Medical directorships for specific services within a product line;
- A host of other medical staff committees—including infection control, surgical review, radiation safety, tissue review, quality/safety/peer review, and so forth.
- On the outpatient side, quality oversight in their own private practices.

Such a proliferation of positions can lead to inefficiency, fragmentation, and conflicting agendas.

The co-management model takes all of those conflicting medical leadership services and wraps them into a global medical leadership contract negotiated on a service line basis. For instance, a co-management agreement for inpatient and outpatient cardiology services would encompass services ranging from the design and imple-
mentation of robust quality/safety programs and measures to development and monitoring of budgets and strategic plans to staffing and supply decision-making. This constellation of services would take a substantial commitment of time from members of the contacted cardiology group (or groups). The group would be compensated for these medico-administrative services at a blended fair market value hourly rate based on standard industry resources (such as the MGMA survey). The contract could include a bonus structure based on achievement of agreed-upon quality/safety goals for the entire continuum of inpatient and outpatient cardiology services for a defined patient population served by the hospital. In other words, the group would be eligible for a bonus not only based on its effectiveness in improving its own physicians' services, but in successfully raising the quality/safety bar for the entire patient population.

A properly structured co-management relationship represents the "next generation" medical leadership agreement in a variety of significant ways, such as:

• Combining multiple types and layers of medical leadership services into a single, integrated agreement;
• Targeting both inpatient and outpatient services—i.e., the full continuum of care;
• Mandating the development and successful implementation of evidence-based clinical protocols throughout the continuum of care;
• Measuring quality/safety success based on the entire patient population, thus holding the medical leaders accountable not only for improving their own care but improving patient care practices on a system-wide basis;
• Building in financial incentives for material gains in quality and safety on a system-wide basis.

The co-management model may offer a helpful first step towards clinical integration by a hospital or health system that is looking for ways to partner with its physicians around safety and quality without taking on major financial risk.

CONCLUSION

The current healthcare delivery system is fragmented, incentive-driven, inefficient and extremely costly. Community hospitals need to partner with their community-based physicians to coordinate their care across the full spectrum of services. We suggest that either the network referral model or the co-management model can offer community health systems a first step along that critically important path.