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Avoiding Marriage: Hospital and Physician Non-Acquisition Financial Strategies

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"Accountable Care Organizations (ACOs)", "The Clinic Model", "The Clinical Care Organization." All of these are terms bandied about today among hospitals, health systems and physicians to refer to some greater measure of affiliation and affinity among them without much clear definition for any of them. We have heard these discussions before. Terms such as "accountable health plans," "enterprise liability" and "integrated delivery networks" described the earlier versions during the period after failed Clinton health reform.

In that time, hospital systems were on buying sprees in anticipation of the sudden need to own primary care physicians. This perception was predicated on the notion that expected capitation payments would flow through those physicians. By owning the physicians, the hospitals believed they would control both the flow of capitated dollars as well as the referral streams to themselves.[1] Many were academic medical centers and tertiary care hospitals which, prior to that moment, had seemed frankly, unsure that primary care was the actual practice of medicine. Their other theory was power in numbers and that with much larger footprints of consolidated institutions and personnel--including physicians--health systems could command better rates from their managed care insurance partners.[2]

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[1] Budetti, et. al, "Physician and Health System Integration," 21 Health Affairs, 203-210 (Jan/Feb 2002)

[2] The Center for Health System Change has been conducting community tracking studies following 12 markets in the United States since 1995. Their reports are an excellent recapitulation of the ebb and flow of strategies we are seeing repeated, today. In 1996 the Center reported health system integration and consolidation as a strategy for hospitals to position themselves for managed care contracting. (Miller, "Health System Integration: A Means to an End", 15 Health Affairs 92-106 (Summer 1996)) By October 1999, the Center was reporting on "Managed Care Backlash" against tight networks and cost control. (Ginsburg, "Managed Care Backlash", 18 J. Hlth Politics, Policy and Law, 1005-1013 (October, 1999)) By this time, primary care physicians were reporting far more demands on them to deliver more complex and a broader scope of care than had been typical. (St. Peter, Reed, Kemper, and Blumenthal, "Changes in Scope of Care Provided by Primary Care Physicians", 341 NEJM 1980-1985 (Dec. 23, 1999)) Shortly thereafter, by April 2000, the Center reported the formation of intermediate provider entities – IPAs, PHOs and other forms of consolidation and affiliation – "to accrue savings that can result from more efficient delivery of care." (Kohn, "Organizing and Managing for Health System Change", 35 Health Services Research 37-52 (April 2000)) But physicians were beginning to have concerns about their ability to deliver quality care in a changing context. (Reschovsky, Reed, Blumenthal and Landon, "Physicians' Assessments of Their Ability to Provide High Quality Care in a Changing Health Care System", 39 Medical Care 254-269 (March 2001)) The managed care entities themselves, though by 2002, had responded by opening access and loosening their networks. (Draper, Hurley, Lesser and Strunk, "The Changing Face of Managed Care, "21 Health Affairs 11-23 (Jan/Feb 2002)) The precipitous decline of system risk contracting occurred contemporaneously. (Hurley, Grossman, Lake and Casalino, "A Longitudinal Perspective on Health Plan-Provider Risk Contracting, "21 Health Affairs (Jul/Aug 2002)) After the publication of the Institute of Medicine report "To Err Is Human", though, the pressures of the marketplace led providers to report that market developments were hindering quality improvement efforts, except for patient safety, which had become much higher profile. (Devers, "Quality Improvement by Providers: Market Developments Hinder Progress," 21 Health Affairs (Sept/Oct 2002))

Some did so well in building cartels that state attorneys general became interested.[3] On the other hand, some of the failures of this strategy, and most prominently the complete collapse of the Allegheny Health System, were quite spectacular.[4] Despite a range of approaches to new ownership, affiliations, management and alliances – horizontal and vertical integration – according to experts "Nothing Worked."[5] Throughout the country, much of what had been bought was cut loose and sold or even given back to the acquired physicians at fire sale prices. Life went on.[6]

Today, there is another sweeping wave of physician practice acquisitions, or merely employment without asset acquisition; but the players and motivations are somewhat different. Physicians—now, many specialists in contrast with the prior era--are beleaguered by falling reimbursement, increased administrative burdens, and the trials of simply managing their practices. They seek financial security and more stability and believe hospitals and health systems can provide it. The objects of their attention – those hospitals and systems – still believe that if they own the workers with the direct relationship to the patients, they can secure their market share and referrals; but now they

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Not long after, the Center reported that since so many systems had already bought primary care physicians, now the phenomenon of hospitals cozying up to specialists with joint ventures and clinical affiliations began to be widespread. (Lake, Devers, Brewster, Casalino,"Something Old, Something New: Recent Developments in Hospital-Physician Relationships", 38 Health Services Research, 471-488 (February 2003)) A year later in 2004, the still independent physicians were found to be consolidating into single specialty groups, particularly in orthopedics and cardiology. (Casalino, Pham, and Bazzoli," Growth Of Single-Specialty Medical Groups", 23 Health Affairs ,82-90 (March/April 2004)) While this positioned those physicians better in relationship to managed care entities for bargaining purposes, two years later defections of physician from practice completely was sufficiently common as to be measurable and reported. (Landon, Reschovsky, Pham, Blumenthal, "Leaving Medicine: The Consequences of Physician Dissatisfaction", 44 Medical Care 234-42 (2006)) The developing fractures in the delivery system were already more acute by December where there was less cooperation and more competition and separation between physicians and hospitals. (Berenson, Ginsburg, May, "Hospital-Physician Relations: Cooperation, Competition or Separation?"26 Health Affairs w-31-w43 (2007, first published Dec 5, 2006)) As late as 2008, though, the Center reported the development of a bi-furcated system with increasing hospital employment of specialists, but the decline of the voluntary medical staff with physicians strongly bonded to their former hospital partners in care delivery. (Casalino, November, Berenson, and Pham, "Hospital-Physician Relations: Two Tracks And The Decline Of The Voluntary Medical Staff Model", 27 Health Affairs 1305-1314. (Sept/Oct 2008))

[3] "Nixon answers antitrust agreement to promote healthcare competition," Missouri Attorney General's News Release (Dec 16, 1994) http://ago.mo.gov/newsreleases/1994/121694.htm; Allen and Farragher, "Partners, insurer under scrutiny," Boston Globe (Jan 23, 2009).

[4] Burns, Cacciamani, Clement and Aquino, "The fall of the house of AHERF," (19 Health Affairs, 7-41 2000)

[5] Burns and Pauly, "Integrated Delivery Networks: A Detour On the Road to Integrated Care?," 21 Health Affairs 128-143 (2002)

[6] Goldsmith, "The Accountable Care Organization: Not Ready For Prime Time," HEALTH AFFAIRS blog, Aug 17, 2009 http://healthaffairs.org/blog/2009/08/17/the-accountable-care-organization-not-ready-for-prime-time/

also are realizing that better financial alignment can produce better measured results. The demand for higher value in terms of measured quality performance, greater efficiency, patient satisfaction, and lowered costs is much more intense than it was in the early to mid 1990s.[7]

Many commentators and consultants who are providing strategic guidance to hospitals, health systems and physician groups, are spurring this fervor for ownership with characterizations of what was learned from the last go around[8], why the current strategies are different[9], with admonitions regarding how to proceed.[10] Yet the acquisition strategy persists, based on the notion that owning the physicians is necessary for better 'alignment' with the hospital. This idea was reinvigorated as the health reform debates intensified regarding "accountability" and "value" with a new emphasis on cost containment if insurance coverage was to be expanded to those not currently insured.

In the health reform debates, there has been a morphing of the concept of 'accountable care organizations' from actual organizational structures[11], to shared savings arrangements[12], to a potentially virtual entity[13]. Of course, in the debate on accountability, the virtualness is also disputed by the proponents themselves.[14] Similarly, with the publication of the provocative Gawande article in the New Yorker[15], the

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[7] See, Loeb, "The current state of performance measurement in healthcare," 16 Int'l J. for Quality in Hlth Care 6-19 (2004). For a brief survey of the development of performance measurement, see, Gosfield, "The Performance Measures Ball: Too Many Times, Too Many Dancers," HEALTH LAW HANDBOOK, 2005 ed., West Group pp. 227-284 for a discussion of the sudden proliferation of measures and measurement programs. For concerns regarding the quality effects of so much measurement, see, Werner and Asch, "Clinical Concerns About Clinical Performance Measurement," 5 Ann of Fam Med. 159-163, (2007) and Kallem and Gons, "Aligning the Demands for Performance Data," 78 J of AHMA 56-60 (Nov/Dec 2007).

[8] Grauman, "Physician-Hospital Alignment in Today's Climate," Board Room Press (April 2009)

[9] Larson, "Physician-Hospital Integration Redux," Hospitals and Health Networks online (April 15, 2008);

[10] Larson, "Defense vs. Offense: Hospital Employment of Physicians," Health Leaders Media, (May 2, 2008); Stroke and Berth, "Something Old as Something New Again: Structuring Physician Practice Acquisitions," Healthcare Fin Mgmt (July 2009) [http://www.hfma.org/hfm/2009archives/month07/HFM0709Feature_Strode.htm?print=on]

[11] Fisher, Steifer, Bynum and Gottleib, "Creating Accountable Care Organizations: The Extended Hospital Medical Staff," 26 Health Affairs W44-W57 (5 Dec 2006)

[12] Fisher, et. al., "Fostering Accountable Health Care: Moving Forward in Medicare," 27 Health Affairs W219-W231 (27 Jan 2009)

[13] Fisher, Davis and Berwick, "Achieving Health Care Reform: How Doctors Can Help," 360 NEJM 2495-2497 (June 11, 2009)

[14] McKethan and McClellan, "Moving from Volume-Driven Medicine Toward Accountable Care," HEALTH AFFAIRS blog (Aug 20, 2009) http://healthaffairs.org/blog/2009/08/20/moving-from-volume-driven-medicine-toward-accountable-care/

[15] Gawande, "The Cost Conundrum," The New Yorker (June 1, 2009) http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande

description of organizations such as the Mayo Clinic, the Cleveland Clinic, and Intermountain Health, among others, as organizations which have demonstrated excellent care at lower cost, proliferated. All of them "own" their physicians in hospital parlance; in fact, they are their physicians, they will tell you.

In blithe denial, sheer ignorance or intentional defiance of the fact that those highlighted organizations were predominately created by physicians and had evolved their cultures and methods over many years, hospitals and health systems began to adopt a new strategic effort to create the "Clinic model". The Carilion Clinic, notably, made a major announcement of its initiative.[16] Many of these undertakings likely have been launched without full consideration of the real implications of these transactions, nor what it will take to make them succeed.[17] Hospitals have felt burdened (or should) by the demand for dollars to be spent in acquisition. There is not enough money available to buy everyone. Not every physician even merits consideration as an employee, if that strategy is the chosen one. But the real problem is that what is driving physicians to seek being purchased won't be fixed by their acquisition. Even simply moving them to an employment model without having to buy their assets won't confront the core dilemma. Inadequate payment from insurers and health plans won't change merely as a result of moving physicians under the health system's wings. Moreover, if hospitals acquire the physicians, but don't change fundamentally what they do, what is the point, other than to secure referrals and perpetuate the existing inadequacies of care delivery? What value is the driving force for the new relationships?

Whatever the organizational forms that emerge, it is generally agreed that the future success of hospitals and physicians is more intertwined than ever.[18] While the desire for "alignment" of their interests is soguht with unprecedented fervor, there is no one way to achieve better results and the sweet spot for both is clearly improved quality and better value.

This chapter takes as its premise that there are multiple, non-employment financial strategies by which hospitals and health systems on one hand, and still independent physicians and groups on the other, can have financial relationships which help both to produce better value in the developing health care marketplace. Still further, these techniques can enhance actual measured performance with improved financial margins to both. These strategies include: (1) hospital payment to physicians[19]; (2)

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[16] Belcher, "Clinical Trial: Supporters and detractors of Carilion's plans seek to win hearts and minds," VA Bus Journal (Jan 7, 2007) http://www.virginiabusiness.com/edit/magazine/yr2007/jan07/hospit1.shtml

[17] Gosfield and Reinertsen, "Informed Consent To The Ties That Bind", The Physician Executive **[pp. __]**

[18] "Physician-Hospital Relationships: Is The Model Broken? Can It Be Fixed?," Hospitals and Health Networks, (Dec 2009) pp. 46-55

[19] This chapter will say very little about gainsharing – the typical payment by a hospital to physicians for assisting in keeping hospital costs down by standardizing supplies in the procedural units.

physicians obtaining personnel from the hospital; (3) hospital support and collaboration with physicians to improve payment from others; and (4) hospital in-kind benefits to physicians – all compliant with Stark and the anti-kickback statute.

_.1 **Hospitals Paying Physicians**

___.1.1 *Paying Physicians for Quality Results*

As demands for demonstrated quality increase, the engagement of physicians with hospitals to improve both of their quality results is increasingly sought by both parties. [20] Gainsharing programs have claimed to be about improved quality but they are fundamentally about saving a hospital money. The restrictions on the operation of gainsharing programs stem from the statutory prohibition on hospitals paying physicians to reduce services, even when the reduction is from a baseline of over use.[21] The OIG originally published a Special Advisory Bulletin castigating the operation of gainsharing programs[22] but eighteen months later issued a positive advisory opinion[23] approving gainsharing programs with safeguards to protect against improper under-service. There were no additional opinions until six were obtained by the same consultant in 2005. [24] Many more positive opinions have been issued since; but all involve short-term programs, because the money comes from savings; once the maximum savings are achieved, then what?

In contrast with saving money for hospitals, hospitals actually paying physicians for improved quality results has been of interest, but many lawyers have been concerned that such payment would be problematic under the Stark statute. When the Medicare fee schedule for 2009 was published in November of 2008, many were expecting the regulators to speak to specific exceptions for gainsharing as well as one for "incentive payments," since proposed regulations had specifically called for comments on point. It was noteworthy that rather than publish two new exceptions, the regulators posed, by their own count, 55 questions on which they sought answers admitting their relative unfamiliarity with these kinds of programs and a desire not to over-regulate and stifle innovation.

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[20] See Reinertsen JL, Gosfield AG, Rupp W, Whittington JW, "Engaging Physicians in a Shared Quality Agenda." IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2007. (Available on www.IHI.org).

[21] 42 USC §1320a-7b

[22] "Gainsharing Arrangements and CMPs for Hospital Payments To Physicians To Reduce or Limit Services to Beneficiaries" OIG (July 1999)

[23] Advisory Opinion 01-01

[24] Advisory Opinions 05-01, 05-02, 05-03, 05-04, 05-05 and 05-06.

In the absence of an explicit exception to pay physicians for quality results, it should be noted that the regulators have already explicitly acknowledged the legitimacy of such payments

> *..[A]s we discussed in Phase II, compensation related to patient satisfaction goals or other quality measures unrelated to the volume or value of business generated by the referring physician and unrelated to reducing or limiting services would be permitted under the personal service arrangements exception, provided that all the requirements of the exception are satisfied (for example, compensation to reward physicians for providing appropriate preventive care services where the arrangement is structured to satisfy the requirements of the exception. (69 FR 16091).* [25]

Although we have no explicit guidance on point, having learned from the relatively tepid results of most pay for performance programs[26], a critical aspect of any one of these programs would be to start with a measured baseline reporting to both the hospital and physicians their starting point. After that, a range of issues ought to be addressed. Set forth here are some ideas about how to structure a Stark compliant program which would pay physicians for hospital quality results.[27]

First, who is eligible to participate should be stated. A program might take into account factors such as how long someone has been on staff in order to have enough data around which to make payments, as well as enough data to determine how much the physician has contributed to the results. While the regulators have expressed concern that allowing staff member participation early upon joining the staff would induce physicians to shift their hospital allegiance to get the quality payment, it is a longstanding performance measurement truism that there has to be a sufficient volume of data on which to measure and draw valid conclusions. To permit payment to individuals in the absence of adequate data would fly in the face of this well known issue. If the payment does not turn on individual performance, however, but on some other basis, then who is eligible to participate is not so cut and dried. In any event, at what point physicians may participate in the program and based on what volume of data should be stated in advance.

The program should be based on a written document identifying 8 key elements: (1) the measures to be applied, (2) for how long it will run until a payment is made, (3)

[25] 72 Federal Register 51046 (Sept 5, 2007).

[26] Rosenthal, "Beyond Pay for Performance – Emerging Modesl of Provider-Payment Reform", 359 NEJM 1197-1120 (Sept 18, 2008); "Medical 'Pay for Performance' Programs Help Improe Care, but Not Always, Study Find", Science Daily Nov 24, 2009
http://www.sciencedaily.com/releases/2009/11/091123171420.htm

[27] Many of these ideas were submitted as my comments to CMS in response to their 55 questions.
http://www.gosfield.com/PDF/incentive.payment.shared.savings.QAs.121208.pdf

the period of time of measurement, (4) the qualifications for physician participation, (5) the calculation of payment to be made, (6) for what targets and/or goals, (7) to whom payment will be made, and (8) a statement as to the baseline of performance before the program begins. For payment to be made there should be a written calculation or statement of the results achieved that relate to the targets or goals, and a record of payments made. If a "quality performance payment program" (QPPP) runs more than a year, the document should be renewed on at least an annual basis for each QPPP. The document should be available to the Secretary of HHS upon request.

The program should use measures that are substantially related to nationally recognized, evidence-based or consensus-based measures (e.g. nationally recognized clinical practice guidelines, NQF measures, etc). The measures to trigger payment need not be limited to those explicit measures but could be based upon them. For example, if a hospital chooses to reward physicians for very quick response times to insert a balloon catheter, that is a component of the hospital's door-to-balloon time, but it is not itself the door to balloon time, which entails many more factors than just when the physician presents to perform the service.

The hospital should conduct on-going monitoring of the program to determine if unintended consequences (e.g., underuse, overuse, misuse) have occurred. "Be careful what you measure" is the quality measurement aphorism for the often noted phenomenon that when measures are used to reward or punish, participants will work to produce good scores, sometimes to the detriment of other care. It would be important to look for ancillary effects from attention to what is rewarded.

Medical staff members should be eligible to be added during the term of a QPPP. These programs might be constructed around service delivery, departmental functions, cross-departmental centers of excellence, or individual performance. Physicians who are contributing to the quality performance of the hospital should be able to participate. Depending on when they joined, and whether they have generated with their care enough data on which to judge their contributions, payments might be made pro-rata to them, depending on how the program is constructed, for the period of time that they have participated.

No physician should be paid based on the volume or value of his referrals, although indirect recognition of referrals is inherent in these programs. Payment should reasonably relate to the measure that is achieved, which would be determined by having a threshold of performance to begin with and then measuring the performance, whether by department, DRG, by individual physician or on any other basis. Hospitals are increasingly subject to payment effects based on quality. From hospital pay for performance programs[28], to cost savings from avoided errors and harms,[29] it is

[28] See, Lindenauer et al, "Public Reporting and Pay for Performance in Hospital Quality Improvement", 356 NEJM 486-496 (Feb 1, 2007); CMS Premier-Hospital Quality Demonstration Project http://www.preimierinc.com/p4p/hqi/

increasingly possible to identify a source of funds from which payments might be made. In addition, new payment models are identifying cost reduction opportunities based on quality improvement. In the PROMETHEUS Payment® program (www.prometheuspayment.org) Potentially Avoidable Complications (PACs)--which are currently being paid for by all insurers--can be identified. In that payment model, providers are given in their budgets one-half the historical amounts paid for those complications[30]. If the providers working together prevent these complications, there is a pool of money at the insurer available to reward them. Even though all stand to benefit from avoided cost and higher quality scores, hospitals can also share their money with physicians.

The OIG has approved a hospital sharing revenues from a commercial pay for performance program with its medical staff.[31] Medicare has launched an Acute Care Episode (ACE) Demonstration that will test the effect of bundling Part A and Part B payments for episodes of care. Although this three year program is explicitly described as a shared savings or 'gainsharing' program, it is focused around specific cardiovascular and orthopedic procedures. So it is not a gainsharing program like the ones the OIG has approved. Based on the bids by the hospital systems involved, 28 cardiac and 9 orthopedic inpatient surgical services and procedures are included in the bundled payment program.[32] By definition, though, this means that if the physicians will get any economic benefit from the program, the hospital will have to give them some of the money it is paid. Turning our attention, now, Moving from payment for improved results, hospitals can pay physicians for services rendered.

___.1.2 *Personal Services*

Both the Stark statute and the anti-kickback statute provide protection for personal services arrangements between physicians and the entities to which they refer. The conditions of both the Stark exception[33] and the safe harbor[34] are similar: there must be a written agreement, signed by the parties; covering all the services provided; with a term of at least a year; with compensation based on fair market value without taking into account the volume or value of referrals between the parties. The safe harbor also establishes that the aggregate compensation must be stated in advance and if the

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[29] Van Dyke, "When Hospital Infections Go Down Pay Raises and Bonuses Go Up at UMC," HFMA (2009) http://www.hfma.org/leadership/WhenHospitalInfections.html

[30] See, Gosfield, "Making PROMETHEUS Payment Rates Real: Ya' Gotta Start Somewhere", http://www.prometheuspayment.org/publications/pdf/MakingItReal-Final.pdf

[31] Advisory Opinion 08-16

[32] See, CMS Press Release, "CMS Announces Sites for Administration to Encourage Greater Collaboration and Improve Quality using Bundled Hospital Payments" (Jan 6, 2009)

[33] 42 CFR §411.357(d)

[34] 42 CFR §1001.952(d)

engagement is periodic that the specific periods must be set forth, their schedule enumerated, and the charges associated with each period stated.

Against this background, a host of personal services arrangements might be established between hospitals and physicians including medical directorships, on-call coverage payments, product line management arrangements, and purchased services where the hospital pays the physicians.

Medical directorships where physicians are paid by the hospital for their time spent in clinical administration of a section (e.g., echocardiography) or a service line (e.g., the back pain program) or a department, have long been used to secure the expertise of physicians in the service of the hospital. Paying medical staff members for their work on hospital initiatives, including even service on medical staff organization committees has also been deployed by some hospitals. Although some organizations, like McCleod Regional Medical Center in Florence, SC have been able to achieve spectacular quality results from their independent medical staff with no payment for service[35], other communities and organizations are not so fortunate. It should be noted, though, that the medical staff organization exists solely to serve the hospital's need for advice to the board on clinical quality issues. Therefore, service in medical staff leadership or on committees can be compensated by the hospital as a benefit to its goals. It is not a benefit to physicians, but rather takes time from their other obligations. Increasingly the traditionally voluntary nature of this service is eroding as the responsibilities of the staff increase to do work beyond mere credentialing—determining whether physician applicants have all their paperwork in order.

A similar development has been the advent of payment for on-call coverage. Traditionally this was something physicians donated to the hospital. As patients became more litigious and more and more patients who showed up at the emergency department were uninsured or had unfavorable insurance, physicians became less and less willing to participate for free in what they increasingly saw as risky activities. Hospitals expanding their programs in trauma and other high specialty services had to be able to secure the availability of required expertise, and the era of paying for on call coverage was launched.[36] By 2008, it was estimated that 30% of hospitals pay for on call coverage[37], but it was not until last year that the OIG finally issued an Advisory Opinion that approved a program which provided for on call pay as well as payment to cover indigent

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[35] See, IHI White Paper, n.20 at 9

[36] See Newman and Anderson "Physician On-Call and Coverage Arrangement: History, Present and Future," HEALTH LAW HANDBOOK, (2010 ed) pp For some background on the pressures that create these circumstances and how hospitals respond see, O'Malley, Draper and Felland, "Hospital Emergency On Call Coverage: Is There A Doctor In the House?", Center for Studying Health System Change, Issues Brief 115 (Nov 2007) http://www.hschange.org/CONTENT/956/

[37] O'Reilly, "AMA Meeting: Delegates explore on-call coverage. At home genetic tests," AMNews (July 7 2008) http://www.ama-assn.org/amednews/2008/07/07/prsh.0707htm.

patients.[38] The program has approved a range of complexities that many hospitals might avoid. It qualifies indigent or underinsured patients. It requires that physicians who seek payment for indigent care participate in call coverage. It establishes a specific schedule for coverage and a fee schedule for the indigent care payment. But the OIG has approved it all, finally clarifying that such payments can be compliant.

When the Stark regulations eliminated from the definition of fair market value the need to peg compensation to the average of four of six compensation surveys, the possibilities for paying physicians equitably for their lost opportunity costs increased. However, these types of arrangements are typically accounted for based on some quantum of time. The problem for physicians is that they are trading professional service time for administrative time, so time-based payments are not necessarily sufficient to protect their lost opportunity costs, which can only be taken into account to a certain extent. Increasingly, physicians will want – and hospitals ought to expect– that payment for their personal services might reflect the results they produce in their work for the hospital. While it is certainly easy to set a base compensation rate for medical directorships to reflect time spent, it is also possible to attach outcomes to compensation now that hospitals increasingly actually experience a payment effect from their improved results.

Another strategy is product or service-line management agreements which go beyond simple clinical administrative efforts associated with the services physicians might provide to hospitals. In these arrangements, the physicians are far more deeply involved in the day-to-day operations of the service line (e.g., interventional cardiology or cancer care) often in parallel with an administrator. Some results from these programs have been impressive from both a quality and cost perspective.[39] Because of the extent of the physician involvement, these agreements also are often conducted between groups and hospitals rather than individuals so the physician workload can be shared. These arrangements also far more typically involve targets for improved quality with differential payments based on those targets.

A different opportunity arises for some entrepreneurial practices. In many settings, sophisticated physician practices have developed better expertise at certain kinds of service delivery than their hospital counterparts; and hospitals are increasingly recognizing this in purchasing management services from those physicians. Physician groups have spun off billing companies through which they help hospitals bill for the physicians they employ. Oncologists have developed clinical trial management companies and have offered their management services to hospitals who are less efficient in their service delivery. Other physicians have succeeded extremely well in developing specialty-type electronic health records or information technology infrastructure and are finding ways to provide these services to hospitals for a fee. All of this can be paid for

[38] Advisory Opinion 09-05
[39] Bahktiari, "Top Cardio Programs Are Physician Led", Health Leaders Media (April 23, 2009) http://www.healthleadersmedia.com/content/231972/topic/WS_HLM2_PHY/Top-Cardio-Programs-Are-PhysicianLed.html

under the personal services protections as well as the fair market value compensation exception under Stark.

___.1.3 *Right of First Refusal*

During the last round of organizational integration after failed Clinton health reform, in many communities around the country there was a mad scramble among competing health systems to purchase primary care practices. These physicians, who had long been step-children in the academic and tertiary hospital world, were suddenly the sought after commodity. All the parties understood that if any one of the suitors succeeded in winning the physicians to their team, the others could kiss any referrals goodbye. In fact, many find it surprising that the Stark regulations explicitly allow entities to restrict referrals to those within the hospital network or system under the personal services exception, the employment exception and the managed care exceptions.[40] In communities where physicians split their referrals among hospitals, there is real value, then, in a hospital assuring that physicians stay independent. This value can be quantified by a third party fair market value evaluator.

The transaction would comply with the fair market value exception. Obviously it could not require referrals. It could be terminable if the group stopped referring although to explicitly do that would implicate the prior payments as having been for referrals. Simple termination without cause might avoid that problem. Such a transaction should be structured as a true right of first refusal with conditions pertaining to a bona fide offer received and considered, giving the compensating hospital a true right to meet the offer as any other right of first refusal agreement might be structured. In fact, in the exception for retention payments in underserved areas to physicians on staff, the conditions that might be applied to a right of first refusal are stated.[41] Turning now to money flowing in the other direction, hospitals can sell services to physicians. Against that regulatory background, some creative approaches to hospital physician relationships can come from physicians leasing personnel from hospitals.

___.2 Physicians Leasing Personnel From Hospitals

Interestingly, the Stark regulations provide an exception for an entity to pay a physician for services performed[42] but not for a physician to pay an entity for the lease of others. Similarly, the fair market value exception under the Stark regulations[43] expects the dollars to flow from the referred to entity back to the physician. There is a different Stark statutory protection for a physician to buy items and services from others, as long

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[40] See 69 Fed. Reg 16069 (March 26, 2004) reconfirmed at 72 Fed Reg. 51030 (Sept 5, 2007)

[41] 42 CFR §411.357(l)

[42] 42 CFR §411.357(d)

[43] 42 CFR §411.357(l)

as the payment is for fair market value[44]. In contrast, the anti-kickback safe harbor, does not distinguish in which direction the dollars are flowing and protects any arrangements between a 'principal' and an 'agent' which are compliant with the safe harbor.[45]

Throughout the country, physicians are consolidating within their groups by expanding their specialty lines. Urologists and gastroenterologists are hiring anesthesiologists and pathologists, respectively. Cardiologists are hiring cardio-thoracic surgeons. Oncologists are hiring radiologists to do their PET scans. Along with these specialty additions, physician groups are adding technologies, although with the degradation in payment for cardiac imaging in particular under Medicare, many groups which previously bulked up their office-based capacities are now looking to unload their equipment, often to the hospital, while they continue to manage the service.

As physician groups look to expand their capacities, some have sought assistance from hospitals in the form of recruitment subsidies. But this support comes with an often intolerable condition imposed by the Stark regulations[46], namely that the physician group cannot impose a geographic restrictive covenant (or at least not an unreasonable geographic restrictive covenant) on the new hire. While there is little clarity about what "unreasonability" might entail, many groups are unwilling to take the risk of having to enforce if a new recruit is unacceptable, but then can set up shop across the street, or not far across town.

There is another way to approach this problem. If the hospital recruits the physician alone and places him in the office of the group where he will eventually work, the hospital takes the financial risk of his being underutilized while he builds a practice. The group pays the hospital on a part-time basis for the services of the physician who reassigns his right to payment to the group, which bills for his professional services. He performs all his professional clinical billable work for the group.

If the physician will be performing designated health services within the group, then he has to render his designated health services on the group's premises, but if he is not performing designated health services, like a surgeon, then these conditions would not pertain. The hospital can utilize the recruited physician for other purposes while he builds his practice. At the end of some predetermined period measured by time or productivity, the physician becomes an employee of the group and no longer works for the hospital. He can work on quality initiatives relevant to the specialty so that when the convent to the group's employment he brings applicable skills and knowledge that can enhance the clinical collaboration between hospital and physician. Confidentiality and non-solicitation clauses can protect both parties during the transition period. The hospital can impose a geographic restrictive covenant on its employee which protects the group if

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[44] 42 USC §1395nn(b)(8)

[45] 42 CFR §1001.952(d)

[46] 42 CFR §411.357(e)(4)(vi)

the relationship does not work out. Another version of this approach does not entail the physician converting to a group employee, but maintains his assignment on a part-time basis to the group for office based work while the hospital bills for his inpatient services. Some cardiology groups are finding this approach to suit their needs.

Similarly, many physician groups---particularly primary care physicians --- would love to add additional mid-level practitioners to their clinical staffing. But, these people --- nurse practitioners and physician assistants predominately – are expensive to recruit and they want benefits. Primary care practices can ill afford these expenses. Hospitals can recruit more easily. Hospitals seek to bond with their primary care referral sources, many of whom often no longer set foot within the four walls of the facility. Hospitals can lease these personnel on a part-time basis to primary care groups (as well as others). These individuals reassign their right to payment to the group when they are working for them and the group bills, while the mid-levels are employed by the hospital. The practice pays on a time basis but bills on a fee basis, providing both hospital and physicians with financial margins on the services as well as the opportunity for the physicians to be saved for their highest and best use. If these individuals are trained in other aspects of the new quality driven environment such as the Wagner Chronic Care Model[47] or the patient-centered medical home[48], they can help these physicians succeed in the new world order..

___.4 **Clinical Integration**

Clinical integration first appeared as a strategic concept in healthcare delivery with the publication of the antitrust safety zones by the Federal Trade Commission with the Department of Justice in 1996.[49] Not actually one of the safety zones, the FTC and DOJ described a fact pattern wherein they would not prosecute even though otherwise competing physicians were bargaining together for fees, because the fee bargain was ancillary to the real reason they came together. Rather than set forth principles for safety, they posited a hypothetical physician network. In the hypothetical, the physicians interacted to measure their performance in accordance with clinical protocols, developed infrastructure to produce data, analyzed the data, took action against the poor performers, and shared the data with the payors with whom they sought to bargain. The development of a multi-provider – hospital(s) with physicians --- network was also reviewed as potentially legitimate.

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[47] Wagner, et al "Improving Chronic Illness Care: Transalting Evidence into Action," 20 Health Affairs pp.64-78 (2001)

[48] See Berenson et al, "A House Is Not A Home: Keeping Patients At The Center of Practice Redesign," 27 Health Affairs pp1219-1230 (2008); see multiple perspectives on the medical home, Health Affairs (Sept/Oct 2008)

[49] "Statements of Antitrust Enforcement Policy in Health Care", Issued by the Justice Department and Federal Trade Commission, Aug. 28, 1996, 5 BNA Health Law Reporter 1265-1327 (Aug. 29, 1996) at 1312-1314

The first advisory opinion issued by the FTC on a proposed arrangement was issued in 2002.[50] Surprisingly, there have only been two more as of this writing. Meanwhile, back in 1996, the AMA was calling for physician unions and all the foment of post-failed Clinton health reform was in the works, with reconfigurations of many provider systems as well as the rise and fall of innumerable IPAs and PHOs all around the country, virtually none of which were actually clinically integrated. In fact, from then until now, the FTC has entered into reams of settlements with IPAs that they said might have been legitimate if they had been clinically integrated.

By 2007, the American Hospital Association itself was calling for greater clarity in what the regulators were looking for as clinical integration.[51] For the most part, the government spurned their request, not wanting to prejudge potential innovation in a new era of transition and change. Now, in response to Congressional inquiry, both the FTC and DOJ have indicated a willingness to provide additional guidance on specific transactions as well as to seek input from the industry and consumers on what works.[52] One of the commissioners characterized their views of clinical integration in a relatively straightforward manner:

> The essence of clinical integration is the interdependence among healthcare providers. Put simply, each provider must have a vested interest in the performance of the other providers, such that their financial and other incentives are closely aligned to meet common objectives. In addition, physicians are more likely to conform their behavior to network goals when their performance is judged by objective standards, in comparison to their peers.[53]

Antitrust lawyers look at these statements differently from quality experts. To quality experts, the essence of clinical integration is clinical collaboration and standardization – the hallmark of almost all currently proposed delivery and payment reform models.[54] From the PROMETHEUS Payment® model[55], to Medicare's pilot program on cardiac

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[50] http://www.ftc.gov/bc/adops/medsouth.shtm

[51] Hogan and Hartson, "Guidance for Clinical Integration" A Working Paper for the AHA (April 2007) http://www.aha.org/aha/content/2007/pdf/070417clinicalintegration.pdf

[52] "DOJ Joins FTC in Signaling Willingness To Provide Additional Guidance for Providers" 18 BNA HL Rptr. (Dec 17, 2009) at 1624

[53] Commissioner Pamela Jones Harbour, Federal Trade Commission, speaking April 27, 2009, to the American Hospital Association.

[54] For an early call for this kind of interaction based on using clinical practice guidelines, evidence-based medicine and standardized care throughout healthcare and not just for quality review purposes see, Gosfield and Reinertsen, "Doing Well By Doing Good: The Business Case for Quality" (June 2003), www.uft-a.com

[55] www.prometheuspayment.org

events[56], the concept of disparate providers working together in the patient's interest to produce high value, efficient, high quality care is the point of the healthcare enterprise.

Much of the emphasis in the discussion of clinical integration has been about competitors working together, because antitrust law is about anti-competitive behavior. There is, however, a completely different way of looking at clinical integration as an approach to changing care delivery--whether any fee bargain is involved or not. Clinical integration is about clinical collaboration among providers whether they are competitors or within the same groups. The whole goal of the acquisition of physician practices in order to bargain for fees, still won't solve the problems of inadequate quality and inefficient organization of care. Hospitals are acquiring practices but many have not focused at all on a different way to deliver care once the structural change has occurred. There is a strong argument for medical groups and hospitals which employ physicians to focus far more on internal clinical integration before they look to work with competitors.[57] That said, in this consideration of hospital-physician non-acquisition strategies, clinical integration can provide important benefits to both.

For hospitals, the coming environment where better quality care is delivered to patients, will reduce many of the admissions they get today. Readmissions within thirty days of discharge are a high profile target for Medicare as well as others. They, among many other admissions, represent 'Potentially Avoidable Complications", a term used in the PROMETHEUS Payment® program to describe services that prior, better care might have prevented, such as admissions for diabetes, diabetic stroke, amputations and eye procedures for diabetic patients. The PROMETHEUS Payment® Program has determined that in the database they use to create--Evidence-informed Case Rates®--their episode of care budget-based payment rates, about 30% of what is spent in this country, just on the 10 conditions they initially modeled into rates, represents this type of care. In a better quality health care system, hospitals will lose these admissions because they are prevented. It is, therefore, imperative that they rethink their business model.

Hospitals and physicians working together can, without engaging in gainsharing programs, significantly improve safety and quality while improving their financial margins as well. The FTC has approved a PHO which involved hospital and physician collaboration.[58] The 'accountable care organization' proposal explicitly expects shared payment, although that aspect of the old world of PHOs is precisely what brought them to ground and under it --- hospitals and physicians fighting over the money. In a properly clinically integrated setting, these disputes can be avoided and mediated based on clinical quality principles. The PROMETHEUS Payment® model actually solves this problem by focusing on bundled *budgets* rather than payments, so otherwise independent providers have an incentive to collaborate, but no one holds the money of anyone else

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[56] See n 31.

[57]Gosfield, "Clinical Integration is back", <u>MGMA Connexion</u> (Nov/Dec 2009) pp. 42-44

[58] Tristate Health Partners Inc. Advisory Opinion (April 13, 2009) http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf

unless they choose to be paid that way. Because the providers contract to provide those portions of the case rate they will manage, it is far clearer as to who is entitled to what portion of the bonus money. The amount of the bonus is based on scores which take into account the care of all providers treating the patient under that case rate.[59] Where providers claim the same portion of the rate, they are forced to work it out between themselves or be paid only the fee-for-service, capitation, DRG or whatever else they have already been paid.

In terms of interactions between hospitals and physicians around clinical integration, in addition to using practice guidelines and evidence-based medicine both to privilege physicians and monitor compliance with quality standards and targets in the hospital, hospitals can help identify protocols and guidelines from which to work. They can facilitate access to hospital infrastructure for monitoring physician conformity, even in their offices, and so, can also help with profiling and creating data to share with payors. They can, compliant with Stark and the anti-kickback statutes, provide staff to support the project, because if these staff work across the boundaries between the hospital and the physician offices, they are not compensation to the physicians, but support for the hospital's own efforts to facilitate its changes. Many lawyers think that if hospitals give anything of value to physicians, that implicates the Stark statute. That is not true. The real test is whether the hospital gives the physicians something of value and benefit *to the physicians.* When hospitals provide training programs for physician leadership --- an increasing phenomenon among hospitals which realize they need medical staff leaders who understand finance, the science of quality improvement, hospital payment methods and more, none of this is usable by physicians in their own lives. It benefits the hospital and therefore is not compensation or remuneration to physicians.

Many wonder how much clinical integration is necessary before they can begin bargaining for fees. The integration does not have to be complete and could be by product-line; so case rates might be bargained for to reimburse for bone marrow transplants, or CABGs, or replacement of hips and knees or all of them without implicating other fees. Still, the integration has to be real before competitors bargain together.[60] By the same token, though, some antitrust lawyers have argued that if you can integrate without having different rates, then you don't need different rates to move forward and the fee bargain is collusive. This seems illogical, since you have to have data to show a payor that what you are doing is real. Then the issue is how far to go before bargaining. The real message, though, is that clinical collaboration and integration --- particularly in ways that save physicians time --- can contribute to improved financial margins and is worth doing even if no one pays differently. It is the essence of the old style large group practice models --- Bassett Healthcare, Scott and White, Geisinger – who are cited as exemplars of 'accountable care organizations'.

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[59] See, Gosfield and de Brantes, "PROMETHEUS Payment: What's The Score?" http://www.prometheuspayment.org/publications/pdf/Whats%20The%20Score.FINAL.pdf

[60] For a very good explication of the basic concepts, including how much is enough, see Leibenluft and Weir, "Clinical Integration: Assessing The Antitrust Risks" HEALTH LAW HANDBOOK, (2004 ed), http://www.gosfield.com/PDF/ch1PDF.pdf

___.5 **Hospital In-Kind Remuneration**

In addition to direct payments to physicians for quality results, services rendered, use of their personnel and more, hospitals can provide physicians with in kind remuneration that facilitates their business case. Two of these that are most significant to quality improvement are (1) compliance training; and (2) electronic health record donations.

It is often overlooked that the hospital can pay for and provide to physicians and their staffs, programs that train them regarding compliance.[61] The educational programs may be made available to a physician or a physician's immediate family member or office staff, where the physician practices in the entity's local community or service area and the training is held in the local community or service area. The breadth of this provision is significant in the current environment since the definition of "compliance training" means:

> Training regarding the basic elements of a compliance program (for example establishing policies and procedures, training of staff, internal monitoring or reporting); specific training regarding the requirements of federal and state healthcare programs (for example billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangement); or training regarding other federal, state or local laws, regulations, or rules governing the context of the party to whom the training is provided.

This last provision opens the door to a host of quality and payment oriented issues where the government now regulates in ways they have not in the past. While traditional compliance topics might include proper claims submission and avoiding false claims as well as appropriate coding and documentation, the issues of clinical integration under the anti-trust laws, state sponsored pay for performance programs, state and federal reporting laws regarding quality and patient safety[62], the Medicare Physician Quality Reporting Initiative, and all aspects of the Stark and Anti-kickback statutes could be incorporated here. In addition, continuing medical education credits may be made available for these programs. This is a seriously underappreciated opportunity for hospitals and physicians to work together to avoid adverse events, quality fraud, false claims and the myriad of targets identified by the enforcers in an effort to save money in the Medicare program.

When the government finally published a relevant safe harbor under the anti-kickback statute and an applicable exception under the Stark statute,[63] hospital electronic

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[61] 42 CFR § 411.357 (o))

[62] See, Shay, "Physician and Hospital Quality Reporting Fraud: Risks and Compliance Methods," HEALTH LAW HANDBOOK (2010 ed) Westgroup pp ______ and Morse and Sheehan, "Mandatory External Reporting of Adverse Events, Near Misses and Unanticipated Consequences," HEALTH LAW HANDBOOK (2007 ed) Westgroup, pp 199-248

[63] 42 CFR §1001.952(y), and 42 CFR § 411.357(w) respectively.

health record (EHR) donations to physicians were expected to be a major boon to the broad dissemination of information technology, widely agreed as essential to improving quality. Demonstration projects were intended to stimulate these moves,[64] with the expectation that physicians would be eager to receive, for far less than what it would cost them to buy the software themselves, assistance in obtaining EHRs. Vendors created incentives[65] as did others to boost these relationships.[66] But there were many gray zones[67] and ill-defined aspects of the protections.[68] With the heightened calls for demonstrated value, controlled expenditures and improved quality, there was even more reason to adopt EHR; but there has been relatively little follow through. Some believe that the government's requirements for fraud and abuse safety to date have been so technical and restrictive that they have thwarted widespread enthusiasm.[69]

The HITECH Act of February 2009, contained significant new incentives in Medicare and Medicaid for hospitals and physicians to adopt "meaningful use" of EHRs,[70] including both financial bonuses for those who do, and for those who don't by 2015, financial penalties. While controversies over "meaningful use" have emerged[71], others criticize the certification processes and agencies charged with blessing these

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[64] Porter, "HHS Targets Communities for HER Pilot Project," AAFP News Now (2/5/2008) http://www.aafp.org/online/en/home/publications/news/news-now/practice-management/20080205leavitt-memphis.html For background on these efforts see, Shay, ""Downstreamed Physician EHR License Agreements: Understanding the Ebb and Flow", HEALTH LAW HANDBOOK (2008 Ed) WestGroup, pp. 45-76.

[65] Amatayakul, "Hospitals Are Selling EHR – But Will Physicians Buy?" HFMA Magazine (9/09) http://www.hfma.org/hfm/2009archives/month09/HFM0909InsideIT.htm

[66] Porter, "EHR Incentive Dollars Flowing to Physicians", AAFP News Now (10/9/2008) http://www.aafp.org/online/en/home/publications/news/news-now/practice-management/20081009ehr-dollars.html

[67] Withrow, "Why can't physicians interoperate? Barriers to adoption of EHRs: the goal of widespread adoption of interoperable electronic health records (EHRs) in the United States remains a mirage,despite new regulations designed to clear the way for such shared information systems," HFMA (2/01/2008) http://www.allbusiness.com/technology/software-services-applications-information/6797139-1.html

[68] See, Kibbe, "Safe Harbor: A Physicians Guide to EHR Donations as Exceptions to the Physician Self-Referral Law and Antkickback Statute (Stark Laws)", NextGen Information Systems, Inc. http://www.centerforhit.org/online/etc/medialib/chit/documents/cme-learn/phyguideehrdonation.Par.0001.File.tmp/PhysiciansGuidetoStark.pdf;

[69] Ackerman, "Could Federal Government Efforts Be Slowing EHR Adoption?", iHealthbeat, (May 28, 2009) http://www.ihealthbeat.org/Features/2009/Could-Federal-Government-Efforts-Be-Slowing-EHR-Adoption.aspx

[70] Pub. L. No 111-5, ARRA Division A Title III

[71] Weinhaus, "Meaningful Use vs. Meaningful Adoption", thehealthcareblog, (July 7, 2009) http://www.thehealthcareblog.com/the_health_care_blog/2009/07/meaningful-use-vs-meaningless-adoption-of-electronic-health-records.html

programs[72], and still others believe that the absence of interoperability standards that are meaningful themselves has been a major barrier to adoption. The National Research Council issued a scathing report on the inadequacies of existing software packages to do what the law was designed to motivate.[73] The state of the art of the EHR industry is apparently not consistent with the vision of the visionaries driving policy.

On the other hand, while adoption may be slow, it is generally agreed to be inevitable. Hospitals and physicians seeking closer bonds in the interests of improved quality and better value cannot walk away from these opportunities without at least considering the potential in moving in this direction. To the extent the providers of healthcare as customers of the vendors hold hands in their demands for improved product, the vendors will be more likely to move.

_.6 Conclusion

There is major change afoot in healthcare delivery and organization. For many hospitals and physicians, they are still each other's significant other and the success of either will depend on the other. With increasingly common demands of them for improved quality and value, they have much in common and can help each other to succeed. While full consolidation of both may work in some settings, success does not require that either 'own' the other in a hierarchical relationship, nor does the law prohibit their financial kindredship. It is time for the parties to focus on the goals of their clinical collaboration and spend less time and money redesigning the boxes and arrows that define their relationships.

[72] See Winthraw, n. 67.

[73] Stead and Lin eds., *Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions,* National Academies Press, Washington, DC. 2009,