

Confluence:

Health Reform or Not, Changes in Physician-Hospital Alignment Are Here

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Whether one believes that elements of the health care industry required reform becomes irrelevant when events and environment catapult the industry towards major cultural change. When there is a confluence of events or circumstances, change is inevitable. The health care industry has experienced a confluence of events which will arguably catapult the industry to shift in a way that focuses seriously on creating innovative structures capable of withstanding the new pressures caused by the confluence of circumstance.

Webster's dictionary defines "confluence" as "a coming or flowing together, meeting, or gathering at one point."¹ What are the events that have caused this change? The Medicare program is still projected to go bankrupt, especially without any legislation that would attempt to slow its growth. State budgets continue to be strained or crippled by various state Medicaid programs, and states cannot pass legislation fast enough sufficient to draw down additional matching funds. Whether or not one advocates for a public option, there is almost universal agreement that fee-for-service payment makes little sense in today's environment, because it promotes quantity, not quality, health care. Employers are starting to demand that the delivery of health care be based on quality metrics, not simply cost, because they know that keeping their employees (and their dependents) healthy will lead to less absenteeism and, in turn, higher productivity.

The past several years have produced studies

and promoted demonstration projects that pay based upon performance and the term "performance" translates directly into quality. For instance, the CMS/Premier Hospital Quality Incentive Demonstration, which provides financial incentives to hospitals demonstrating high quality in certain areas of acute care, resulted in hospitals raising their quality indices by over 17% over four years in certain care areas, resulting in bonus payments of almost \$30 million.²

These alternatives are not sought solely in the public sector. In our own backyard, the Cleveland Clinic and Lowe's Companies recently announced an agreement where Lowe's full-time employees and their covered dependents enrolled in the company's self-funded medical plan may elect to schedule qualifying heart surgery procedures at the Cleveland Clinic in Cleveland, Ohio at an enhanced benefits coverage level.³ In the press release announcing the agreement, Bob Ihrie, Lowe's senior vice president of employee rewards and services, said "We believe that having the correct diagnosis, combined with surgery by the undisputed leaders in this field, will produce the highest-quality outcomes for our employees. By enabling access to top quality care, it is our hope that employees and their dependents will have an improved quality of life for many years to come."⁴ The focus was clearly on quality, with higher quality and better outcomes both lowering costs and getting employees back to work sooner.

This article outlines the reimbursement trends driving the need to align, discusses the role of clinical integration in alignment strategies, and explores three innovative models for physician-hospital alignment. There are nuances to each model and each implicates traditional health care legal land mines (tax, fraud and abuse, reimbursement and antitrust).

I. Reimbursement Trends Driving Alignment

Without question, healthcare expenses are growing, and with them, federal healthcare program expenditures. The Kaiser Family Foundation estimates that Medicare alone, currently 3.6% of the United States Gross Domestic Product (GDP), will grow to 4.2% of GDP by 2018 and to 6.4% of GDP by 2030.⁵ At the current growth rate, the Medicare Part A Hospital Insurance Trust Fund is projected to be insolvent by 2017.⁶ Simply put, without a reduction in costs or other reforms, Medicare may not survive another decade.

This reality is reflected in reimbursement trends over the past few years, particularly for physicians. Medicare physician reimbursement has increased a mere 0%, 0.5% and 1.1% for calendar years 2007, 2008 and 2009, respectively.⁷ As small as these increases were, each was a result of last-minute legislative intervention, without which the statutorily-calculated adjustments would have been approximately -5%, -11%, and -5%, respectively.⁸ Even graver is the 2010 Medicare Physician Fee Schedule (MPFS) Final Rule, which calls for a 21% cut

in physician reimbursement effective February 28, 2010.⁹ While the national average for Medicaid physician reimbursement has fared slightly better, with average yearly increases of approximately 2.5% for calendar years 2003 through 2008, only primary care provider reimbursement grew at the rate of inflation.¹⁰ Even with a slightly higher yearly increase, average Medicaid fees across the United States remain only 69% of Medicare fees for the same services.¹¹

Hospitals have fared slightly better than physicians in recent years, but that is changing as well. For 2010, hospitals are facing a mere 2.1% increase in OPSS payments and a nearly zero, if not negative, adjustment in IPPS payments.¹² Looking forward, if healthcare reform legislation were to pass, it will likely result in sustained, stagnant reimbursement for hospitals. Both the House's Affordable Health Care for America Act of 2009 (H.R. 3962) and the Senate's Patient Protection and Affordable Care Act (H.R. 3590) call for reductions to the Medicare market basket updates to inpatient hospital reimbursement, as well as cuts to Disproportionate Share Hospital payments.¹³ Without health care reform legislation, there will be continued cuts, as outlined by President Obama's budget. As these trends demonstrate, physicians and hospitals alike will be facing a do-more-with-less scenario for the foreseeable future, and one way to save cost is through the efficiencies inherent in alignment.

II. The Role of Clinical Integration in Alignment Strategies

Despite the recent increase in physician employment by hospitals and health systems, healthcare remains very fragmented, making it difficult to achieve gains from treatment efficiency, effectively manage care, avoid duplication, and focus on quality. To achieve many of the goals of health reform, entities that are otherwise competitors must collaborate. The natural extension of this collaboration is jointly negotiating with commercial payors and employers to manage the delivery of healthcare. Ordinarily, this joint negotiation may be considered price-fixing, which is generally a *per se* unlawful restraint on trade under the Sherman Act,¹⁴ unless the potential pro-competitive efficiencies of the integrated network outweigh the anticompetitive effects of the price agreement. Any clinical integration model must pass this test, called the "rule of reason."

The position taken by the Department of Justice (DOJ) and Federal Trade Commission

(FTC) with respect to clinical integration began taking shape in 1999.¹⁶ In their Statements of Antitrust Enforcement Policy in Health Care (1996 Statements), the DOJ and FTC indicated that joint contracting plans for non-financially integrated networks will pass antitrust muster if: (1) the clinical integration is likely to produce significant efficiencies that benefit consumers; and (2) any price agreements with payors are reasonably necessary to realize those efficiencies.¹⁷ Since the 1996 Statements, guidelines, reports and speeches issued by the FTC have both reaffirmed the acceptance of clinical integration and attempted to sharpen the characteristics of a clinical integration program.

The FTC has also approved several specific clinical integration scenarios, the most recent being on behalf of Tri-State Health Partners in 2009.¹⁸ In its decisions, the FTC has found the following characteristics to be persuasive hallmarks of clinical integration: (1) systems and programs to improve quality and efficiency, including (a) clinical guidelines and practice standards, (b) a web-based clinical-information system, and (c) referral requirements and/or guidelines; (2) the network is selective in choosing participants, by (a) utilizing a participating provider contract and (b) limiting participation to fully committed providers in a variety of specialties; (3) a significant investment of capital by participants, both (a) monetary capital and (b) human capital; (4) mechanisms for evaluating performance and facilitating continuous progress, including (a) the use of performance metrics, (b) identifying benchmarks for comparison, (c) using the system infrastructure to facilitate evaluation, and (d) having a follow-up action plan; (5) a pricing agreement that furthers the integration of the network; (6) non-exclusivity, unless it is so small that an exclusive arrangement would not be anticompetitive; and (7) steps are taken to maintain the confidentiality of participating providers' pricing information so that participants cannot enter into collateral agreements, thus preventing "spillover effects" from affecting the market.¹⁹

TriState Health Partners, Inc., a physician-hospital organization located in Hagerstown, MD, sought FTC approval for an arrangement aimed to: facilitate cooperation and collaboration among its member physicians; create a comprehensive program of care management by engaging everyone associated with TriState; and offer a previously unavailable integrated set of services desirable to self-insured employers who want to lower healthcare costs

in an effort to offer a competitive advantage over other health plans.²⁰ Pursuant to the proposed arrangement, TriState would create clinical practice guidelines to improve clinical efficiency as well as a program to monitor the physicians' adherence to those guidelines.²¹ Physicians would be required to refer their patients to other member physicians (though the patient still had the choice of which physician to select) and to grade their peers.²² TriState also proposed the implementation of a web-based health information technology system that will help identify high-risk and high-cost patients and facilitate the exchange of patients' treatment and medical management information.²³

The FTC, in part guided by the 1996 Statements, determined that it would not challenge TriState's proposal due to three principal reasons:

- The program had the potential to lower healthcare costs and improve the quality of care for patients;
- TriState's collective negotiation of contracts with payors, including the prices paid for participating physician services, would be "subordinate and reasonably related" to the overall proposal to integrate healthcare for its members, prompting application of the rule of reason; and
- There would not be an increase in the market power of either TriState or the physician members as a group because all concerned were still free to contract individually outside the proposed program.²⁴

Accordingly, the FTC determined that it would not recommend the commencement of any legal enforcement action against TriState or its providers as long as the proposed plan was followed and no anti-competitive activities, like the exercise of market power, arose.

Although no bright line test exists, the FTC is clearly comfortable with clinical integration models, which will facilitate new models of alignment involving independent physicians, health systems and their employed physicians. The challenge for these parties is going the extra yard, to ensure that the clinical integration is pure and not simply a facade for collaboration among competitors.²⁵

III. Three Innovative Models For Physician-Hospital Alignment

While the DOJ and FTC have become comfort-

able with clinical integration, both Congress and the Centers for Medicare and Medicaid Services (CMS) have advanced from comfort to active promotion of physician-hospital alignment. A number of cost savings initiatives in today's healthcare reform proposals are targeted at improving efficiency through alignment. Following are three such models. The first two models, gainsharing and co-management, have been used in limited form the past several years, and its likely the confluence of events will force their expansion. The final model, the Accountable Care Organization, is much more expansive in integration than gainsharing and co-management (although incorporating elements of each). There is significant focus on the creation of the Accountable Care Organization models and a great deal of interest, as delivery models evolve.

A. Gainsharing

Gainsharing involves the payment of incentive bonuses typically to physicians or other practitioners by hospitals, which payment represents a share of the savings incurred directly as a result of collaborative efforts between the hospital and the physician to improve overall quality and efficiency.²⁶ CMS views permissible "gainsharing" as methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to beneficiaries and to develop improved operational and financial hospital performance with sharing of gains.²⁷ Though such payments potentially implicate the federal Civil Money Penalties Act (CMP), the Anti-Kickback Statute (AKS) and the Physician Self-Referral Statute (Stark), the Department of Health and Human Resources, Office of Inspector General (OIG) has issued at least fourteen Advisory Opinions approving gainsharing plans since 2001.²⁸

These approved gainsharing plans largely focused on standardization of devices, medications and supplies used for particular procedures.²⁹ For example, the most recent opinion outlines a program, involving a hospital, an interventional radiology group and a vascular surgical group, designed to share the hospital's cost savings directly attributable to certain changes in the groups' cardiac catheterization procedures.³⁰ Specifically, these changes involved standardization of the types of cardiac catheterization devices and supplies (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators) employed by

the groups to perform catheterizations at the hospital.³¹ In approving this program, the OIG cited a number of safeguards designed in the program to prevent underutilization and overutilization and ensuring patient safety.³² Such safeguards included the following:

- The parties agreed to use independent third party to administrate the program, including developing the cost savings metrics and measuring cost savings during the program;
- Preferred products would be chosen first based on safety, then on cost;
- Quality would be continuously monitored, with a drop in quality indicators resulting in termination of gainsharing payments;
- Physician productivity would be compared to historical data, preventing overutilization;
- Cost savings would be measured on an initiative-specific basis, preventing cost-shifting;
- Aggregate payments to physicians would be capped; and
- The program would be disclosed to all affected patients.³³

Similar safeguards were present in the other thirteen proposed gainsharing programs, and the OIG advised each time that the program met muster under the CMP, AKS or Stark.³⁴

In 2005, Congress and CMS took this permissive view of gainsharing one step further. Pursuant to a mandate included in Section 5007 of the Deficit Reduction Act of 2005 (DRA), CMS solicited up to six gainsharing demonstration projects, each consisting of one hospital.³⁵ The solicitation asked hospitals to propose gainsharing programs CMS could follow and evaluate to determine if gainsharing "aligns incentives between hospitals and physicians in order to improve the quality and efficiency of care," while improving hospital operational and financial performance.³⁶ To date, two projects have been accepted into the program – one at Beth Israel Medical Center in New York and one at the Charleston Area Medical Center in West Virginia. While the demonstration project is set to expire on December 31, 2009, both H.R. 3962 and H.R. 3590 propose to extend it through September 30, 2011. Such commitment by Congress suggests that gainsharing may prove to be an increasingly important cost-savings tool for physicians and hospitals going forward.

B. Co-Management

A variety of alignment models are emerging to accommodate the integration of payment, quality and efficiency. One, which has been present for some time but whose importance has increased, is clinical co-management. Clinical co-management is a relationship between a hospital or health system and either a physician group or collection of physicians, that combines the clinical principles of pay-for-performance and the market drivers of risk and reward. The hospital or health system is able to use physician expertise to develop better care paths and better outcomes, and physicians are able to become actively engaged in managing a service line and receive compensation for their time and goal achievement.

There are a variety of legal structures, capitalization models and committee models that can be used, and it is really dependent upon the service line and the issues that co-management model will address. However, in developing a clinical co-management model, it is essential that the health system and physicians first focus on the outcomes and behaviors that are desired, not the compensation that will be paid. The parties need to develop measurable and actionable goals and objectives for a service line, along with a committee structure wherein both the physicians and hospital are actively managing a service line. The reimbursement determination will follow, with the physician entity being paid a base rate for the physician's involvement. There will also likely be an at-risk portion of compensation based on overall qualitative performance in improving the service line.

The standard caveats related to fraud and abuse and, if applicable, tax-exemption, apply to co-management models. However, the arrangement can be structured to comply with safe harbors under both the Anti-Kickback Statute and Stark Law. Additionally, the Office of the Inspector General, in Advisory Opinion 08-16, approved an arrangement whereby a hospital sought to share a portion of a quality-based incentive received by a hospital from an insurer with a group of physicians.

C. Accountable Care Organizations

As healthcare reform continues to evolve, another innovative alignment model likely will emerge: Accountable Care Organizations (ACO). Experts define groups of providers (such as combinations of hospitals, physicians, and other health care providers) that are jointly responsible, through shared penalties or bonuses, for the quality of the health care delivery for a specific population of beneficiaries, as an

accountable care organization. As referenced more specifically below, Medicare has been one of the proponents of this model and has funded demonstration projects, the Medicare Physician Group Practice Demonstration to test the pay for performance incentives associated with this model. Results from the demonstration indicate that the model shows promise for containing costs while simultaneously increasing patient outcomes.

An ACO could include a hospital, physicians, both primary care physicians and specialists, and possibly other medical professionals.³⁷ Services provided by these physicians would be billed fee-for-service, but the participants in the ACO would coordinate their care and have goals related to quality benchmarks.³⁸ Examples of such benchmarks may include low mortality rates or reducing hospital readmissions.³⁹ Members of an ACO would share in any cost savings or Medicare incentive payments made as a result of meeting its benchmarks, as well as any Medicare penalties imposed as a result of failing to meet its benchmarks.⁴⁰

The ACO structure will differ depending upon its goals and market and, to truly be maximized, will likely require changes to fraud and abuse laws and potentially more concrete antitrust guidelines. However, it will involve a single entity that will be owned by healthcare providers. The single entity will enter into participation agreements with payors (including, potentially, governmental payors), and have comprehensive clinical and quality guidelines and robust information technol-

ogy systems. While ACOs could be integrated delivery systems, they can also take advantage of clinical integration and include independent physicians.

In its June, 2009 report to Congress, the Medicare Payment Advisory Commission dedicated a chapter to the benefits of ACOs.⁴¹ Several prominent organizations, including the Dartmouth Institute for Health Policy and Clinical Practice and the Engelberg Center for Health Care Reform at Brookings Institution, are instituting pilot programs to test the ACO concept.⁴² Additionally, a current proposal suggests that Medicare may tie both bonuses and penalties to and payments as a result of an ACO meeting or failing to meet the benchmarks.⁴³ Congress is receptive to such a program because it would give Medicare substantial leverage over providers to improve quality. If enacted, H.R. 3962 would direct Medicare to issue incentive payments to qualifying ACOs for meeting what it calls "performance targets."⁴⁴ H.R. 3590 also includes an ACO demonstration project, but it is targeted to pediatric ACOs.⁴⁵ Innovative health systems and physician groups likely will start planning now for ACOs.

IV. Conclusion

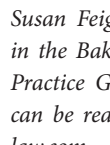
As reimbursement trends and increasing costs require physicians and hospitals to do more with less, investigating alternative alignment models may offer a solution to this demand. Regulators, Congress and a growing number of physicians and hospitals are looking to the efficiencies inherent in greater hospital-physician

alignment to generate substantial cost savings. Through models such as gainsharing, co-management and accountable care organizations, hospitals and physicians may collaborate to provide safe, quality care more efficiently.

Moreover, the failure of Congress to pass comprehensive health reform legislation will not slow the need or the momentum that has begun in the health care industry to move in a direction that more closely integrates care. The health care industry recognizes that payment reform and greater potential belt-tightening require innovative thinking and realignment.



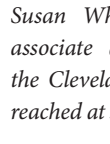
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¹ Merriam-Websters Online Dictionary, available at: www.merriam-webster.com/dictionary/confluence.

² Premier website: <http://www.premierinc.com/quality-safety/tools-services/p4p/hqi/index.jsp>

³ See Lowe's Companies press release dated February 16, 2010.

⁴ *Id.*

⁵ *Medicare Spending and Financing Fact Sheet*, Kaiser Family Foundation (May 2009), available at: www.kff.org.

⁶ *Id.*

⁷ See, 2010 Medicare Physician Fee Schedule Final Rule, available at: www.federalregister.gov/OFRUpload/OFRData/2009-26502_PI.pdf; and Conversion Factor, CCH Med-Guide ¶ 3410 (2009).

⁸ See *id.*

⁹ See *id.*

¹⁰ Karen E. Stockley, Aimee F. Williams & Stephen Zuckerman, *Trends in Medicaid Physician Fees, 2003-2008*, Health Tracking (April 28, 2009).

¹¹ *Id.*

¹² See, 2010 OPFS Final Rule, available at: www.federalregister.gov/OFRUpload/OFRData/2009_26499_PI; 74 Fed. Reg. 43,754 (Aug. 27, 2009); and CCH Med-Guide No. 1559 (2009).

¹³ Affordable Health Care for America Act of 2009, H.R. 3962 §§ 1103; 1112 and 1131; and Patient Protection and Affordable Care Act, H.R. 3590.

¹⁴ 15 U.S.C. § 1, *et seq.*

¹⁵ See, *FTC v. Indiana Federation of Dentists*, 476 U.S. 447 (1986).

¹⁶ See, Statements of Antitrust Enforcement Policy in Health

Care, DOJ and FTC (Aug. 1999), available at www.justice.gov/atr/public/guidelines/0000.htm.

¹⁷ *Id.*

¹⁸ See, e.g. TriState Health Partners, Inc., FTC Advisory Op. (Apr. 13, 2009), available at www.ftc.gov/os/closings/staff/090413tristatealetter.pdf; Greater Rochester Independent Practice Association, Inc., FTC Advisory Op. (Sept. 17, 2007), available at www.ftc.gov/bc/adops/gripa.pdf; MedSouth, Inc., FTC Advisory Op. (June 18, 2007), available at www.ftc.gov/bc/adops/070618medsouth.pdf; MedSouth, Inc., FTC Advisory Op. (Feb. 19, 2002), available at www.ftc.gov/bc/adops/medsouth.shtm; Suburban Health Organization, Inc. (Mar. 28, 2006), available at www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf.

¹⁹ See *id.*

²⁰ TriState Health Partners, Inc., FTC Advisory Op. (Apr. 13, 2009), available at www.ftc.gov/os/closings/staff/090413tristatealetter.pdf.

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ DRA 5007 Medicare Hospital Gainsharing Demonstration Solicitation, CMS, available at www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/DRA5007_Solicitation.pdf.

²⁷ *Id.*

²⁸ See *OIG Adv. Op.* 01-1 (2001); *OIG Adv. Op.* 05-02 (2005); *OIG Adv. Op.* 05-03 (2005); *OIG Adv. Op.* 05-04 (2005); *OIG Adv. Op.* 05-05 (2005); *OIG Adv. Op.* 05-06 (2005); *OIG Adv. Op.* 06-22 (2006); *OIG Adv. Op.* 07-21 (2007); *OIG Adv. Op.* 07-22 (2007); *OIG Adv. Op.* 08-09 (2008); *OIG Adv. Op.* 08-15 (2008); *OIG Adv. Op.* 08-16 (2008); *OIG Adv. Op.* 08-21 (2008); and *OIG Adv. Op.* 09-06 (2009).

²⁹ *Id.*

³⁰ *OIG Adv. Op.* 09-06 (2009).

³¹ *Id.*

³² See *id.*

³³ See *id.*

³⁴ *Id.*

³⁵ See *supra* note 22.

³⁶ *Id.*

³⁷ Jane Cys, *Accountable Care Organizations: A New Idea for Managing Medicare*, American Medical News (Aug. 31, 2009).

³⁸ *Id.*

³⁹ James Arvantes, *MedPac Considers Accountable Care Organizations as Possible Path to Health Care Reform*, AAFP News Now (April 20, 2009).

⁴⁰ See *supra* notes 33, 35.

⁴¹ See *supra* note 33.

⁴² *Id.*

⁴³ See *supra* note 35.

⁴⁴ H.R. 3962 § 1301.

⁴⁵ See H.R. 3590 § 2706.