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ALIGNING HOSPITAL AND PHYSICIAN INCENTIVES IN THE ERA OF PAY-FOR-PERFORMANCE

William H. Thompson, Esq.*

I. INTRODUCTION

Known variously as pay-for-performance, pay-for-quality, or quality contracting, these reimbursement models tie provider payments to patient care as measured by specific criteria, such as clinical process standards, patient satisfaction, patient outcomes, deployment of information technology, and a host of other measures. There are now a number of initiatives underway by commercial insurers, the Medicare and Medicaid programs, employers, and other payers of health care services based on pay-for-performance principles. This payment methodology is a radical change from the current system of reimbursement, which is best described as payment for inputs regardless of the outcomes. The pay-for-performance ("P4P") movement is the latest in a long and difficult search for a rational system to reimburse hospitals, physicians, and other providers of health care services.

So, what is a hospital to do in the face of an emerging system of reimbursement that is going to be based increasingly upon quality outcomes, efficiency measures, deployment of information technology, and patient satisfaction; particularly when the hospital has little direct control of the care processes and decisions that affect such measures? This dilemma was summarized well by Dr. Charles Peck:

> Physicians and hospitals collectively suffer from "mural dyslexia," characterized by an inability to read the handwriting on the wall. The handwriting is indeed clear. To survive, hospitals must collaborate with doctors because the most expensive piece of medical technology is the physician's pen. In turn, to survive, doctors must collaborate with someone, and the hospital remains the natural partner.[1]

To be sure, hospitals should seek to align incentives with their physicians and other providers in order to maximize their success under a reimbursement system based on pay-for-performance principles. This alignment is easier said

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1. Charles A. Peck, *The Enterprise Circle*, PHYSICIAN EXECUTIVE, Jan. 2001.

than done. However, the effort should not be futile. Regardless of the payment system, initiatives aimed at improving quality outcomes, patient safety, and efficiencies are noble in purpose and worthy of pursuit. It is about time that sound clinical practice drives the reimbursement system, instead of the other way around.

This article will explore several hospital/physician alignment strategies and the legal and policy considerations that must be addressed in the new world order of pay-for-performance.

II. THE ADVENT OF PAY-FOR-PERFORMANCE

The vast majority of the United States private and governmental reimbursement systems are structured on the basis of separate payments to each provider involved in the care of a patient. Under these systems, the physician receives payment for his or her professional services based on a fee schedule. For example, the doctor is paid on inputs and the hospital receives payment for its services based on a diagnosis-related group, per diem, case rate, or percent of charges for inpatient and outpatient services. Thus, the more care given to the patient, generally the more reimbursement received. The rehab provider in turn is paid separately, as is the home health care provider, and so on. There is little rationale behind this payment system with regard to an episode or continuum of care, even though the outcome of each provider's efforts, with regard to such care, is largely interdependent upon the efforts of the other providers involved in the patient's care.

Under today's system of reimbursement, "coordination of care across the continuum," as it is commonly referred, is a principle that largely rings hollow.[2] Financial incentives are geared more toward treating symptoms than controlling diseases (particularly chronic diseases) or achieving favorable outcomes.[3] The P4P movement may provide an opportunity to rationalize payment and outcome. Pay-for-performance initiatives will not solve all (or any?) of the ills of our American health care system. It may, however, be an experiment worth trying.

In 2001, in the report *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine ("IOM") called upon health system stakeholders to develop new payment systems that align providers' incentives with the goal of quality improvement.[4] This request was in part a response to a previous IOM report published in 1999, *To Err is Human: Building a Safer Health System*, which focused on patient safety.[5] One of the IOM's recommendations for transforming health care quality in the

2. *See* Paul Krugman, *First, Do More Harm*, N.Y. TIMES, Jan. 16, 2006, at A15.

3. *Id.*

4. INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001) [hereinafter CROSSING THE QUALITY CHASM].

5. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (1999).

United States is to align payment policies with quality improvement. This recommendation calls for "all purchasers, both public and private to carefully reexamine their payment policies to remove barriers that impede quality improvement and to build in stronger incentives for quality enhancement."[6]

The IOM's *Crossing the Quality Chasm*[7] makes clear the need for a systematic and radical overhaul of health care. Furthermore, there is a growing consensus that quality can no longer be ignored when it comes to provider payment. Advocates believe that the future of the American health care system is dependent upon a payment system that measures, compares, and rewards performance, not in terms of the number or complexity of services rendered, but instead on the basis of the quality and efficiency of such services.[8]

The concept of paying providers for performance (however measured) is being explored and implemented by both private and governmental payers alike. The Medicare Payment Advisory Commission ("MedPAC"), an advisory arm of the United States Congress, advocated in June, 2003 that Medicare begin using incentives to improve the quality of health care.[9] MedPAC recommended that a pay-for-performance system in Medicare begin with health plans and rehabilitation facilities because they have the history and capacity to collect and publicly report the quality data necessary for performance measurement.[10] MedPAC has elaborated on its recommendations in subsequent reports and testimony before the House Ways and Means Committee:

> Current payment systems in Medicare are at best neutral and at worst negative toward quality. All providers meeting basic requirements are paid the same regardless of the quality of service provided. At times providers are paid even more when quality is worse, such as when complications occur as a result of error. It is time for Medicare to take the next step in quality improvement and put financial incentives for quality directly into its payment systems.[11]

Consistent with MedPAC's recommendations, the Centers for Medicare and Medicaid Services ("CMS") has embarked on a number of demonstration

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6. CROSSING THE QUALITY CHASM, *supra* note 4.

7. *Id.*

8. Jack Ebeler, American Bar Association Teleconference Discussing Paying for Performance to Improve Healthcare (May 2, 2005) (transcript on file with author).

9. MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: VARIATION AND INNOVATION IN MEDICARE (2003).

10. *Id.*

11. *Improving Quality through Medicare and Payment Policy: Hearing Before the Subcomm. on Health Comm. on Ways and Means, U.S. House of Representatives*, (Mar. 18, 2004) (statement of Glenn M. Hackbarth, Chairman Medicare Payment Advisory Commission).

projects and pilot programs concerning pay-for-performance programs.[12] These programs include:

- Premier Hospital Quality Incentive Demonstration.
- Physician Group Practice Demonstration.
- Medicare Care Management Performance Demonstration.
- Medicare Health Care Quality Demonstration.
- Chronic Care Improvement Program.
- Disease Management Demonstration for Severely Chronically Ill Medicare Beneficiaries.
- Disease Management Demonstration for Chronically Ill Dual-Eligible Beneficiaries.
- End Stage Renal Disease (ESRD) Management Demonstration.
- Care Management Demonstration for High Cost Beneficiaries.[13]

A component of each of these demonstration projects is the adoption of standard quality measures to support better care coordination and continuity for beneficiaries with chronic or acute illnesses across different settings.[14] Each project is piloting various payment reforms to reward providers for better quality, better patient satisfaction, and lower overall costs.[15] The number and scope of these demonstration projects is indicative of CMS' desire to revamp the Medicare program in an attempt to reconcile payment and quality.

Private insurers of health care services are also embarking on reimbursement programs that attach payment to certain measures of care. These programs range in scope from national initiatives underwritten by private foundations, such as the "Rewarding Results" program funded in part by the Robert Wood Johnson Foundation, which is intended to assess and develop innovative reimbursement models to single payer efforts with less ambitious goals of securing the bottom line.[16] There is, however, one aspect that is common to all private P4P programs: the objective of assisting purchasers of

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12. *See* Enclosure 3 of letter from Mark B. McClellan, Adm'r of Ctrs. for Medicare and Medicaid Servs., to William M. Thomas, Chairman of Ways and Means Comm., U.S. House of Representatives (June 24, 2005).

13. *Id.*

14. *Id.*

15. *Id.*

16. *See* Leap Frog Group, http://www.leapfroggroup.org/RewardingResults/index.htm (last visited Mar. 6, 2006) (for an overview of *Rewarding Results*, which is a privately funded $8.8 million national pay-for-performance project with many types of health care providers and payers).

health care and health plans to align incentives for high-quality health care.[17] The prevalence of P4P programs in the private sector depends in part upon geography; but based on a recent survey by *Medical Economics*, it is clear that a number of commercial insurance companies are implementing pay-for-performance measures in their health services contracts.[18] Advocacy groups for insurance companies and other payers of health care services have also endorsed the P4P principles, including the Leapfrog Group, Bridges to Excellence, and the Integrated Healthcare Association.[19] No doubt, private insurers will continue to push pay-for-performance programs as long as the data shows these programs result in reduced costs and better care to their insureds.

As the national debate intensifies over pay-for-performance programs, many professional societies and accrediting bodies have weighed in with their views and proposed standards. For example, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") has set forth ten principles that it offers "to guide the development and refinement of current and pay-for-performance programs."[20] These principles are applicable to P4P programs initiated by payers as well as to hospital/physician alignment strategies that are aimed at incentivizing improved quality and patient safety. The principles are as follows:

- The goal of pay-for-performance programs should be to align reimbursement with the practice of high quality, safe health care for all consumers.
- Programs should include a mix of financial and non-financial incentives (such as differential intensity of oversight; reduction of administrative and regulatory burdens; and public acknowledgment of performance) that are designed to achieve program goals.
- When selecting the areas of clinical focus, programs should strongly consider consistency with national and regional efforts in order to leverage change and reduce conflicting or competing measurement. It is also important to attend to clinical areas that show significant promise for achieving improvements because they

17. *Id.*

18. Ken Terry, *Pay-for-Performance: How Fast Is It Spreading?*, MED. ECON., Nov. 4, 2005; *see also Pay for Performance Works, Says CMS... But Challenges Persist, Says Study*, J. HEALTHCARE FIN. MGMT., Jan. 2006, at 17-20 [hereinafter *Pay for Performance Works*].

19. *Pay for Performance Works*, *supra* note 18.

20. Joint Commission on Accreditation of Healthcare Organizations, *Principles for the Construct of Pay-for-Performance Programs*, http://www.jcaho.org/about+us/public+policy+initiatives/pay_for_performance.htm (last visited Mar. 6, 2006).

represent areas where unwarranted differences in performance have been documented.

- Programs should be designed to ensure that metrics upon which incentive payments are based are credible, valid and reliable.
- Programs must be designed to acknowledge the united approach necessary to effect significant change, and the reality that the provision of safe, high quality care is a shared responsibility between provider organizations and health care professionals.
- The measurement and reward framework should be strategically designed to permit and facilitate broad-scale behavior change and achievement of performance goals within targeted time periods. To accomplish this, providers and practitioners should receive timely feedback about their performance and be provided the opportunity for dialogue when appropriate. Rewards should follow closely upon the achievement of performance.
- Programs should reward accreditation, or have an equivalent mechanism that recognizes health care organizations' continuous attention to all clinical and support systems and processes that relate to patient safety and health care quality.
- Incentive programs should support an interconnected health care system and the implementation of "interoperable" standards for collecting, transmitting and reporting information.
- Programs should incorporate periodic, objective assessment into their structure. The evaluations should include the system of payment and incentives built into the program design, in order to evaluate its effects on achieving improvements in quality, including any unintended consequences. The program and, where appropriate, its performance thresholds should be re-adjusted as necessary.
- Provisions should be made to invest in sub-threshold performers who are committed to improvement and are willing to work themselves or with assistance to develop and carry out improvement plans. Such investments should be made after considering both the potential for realistic gains in improvement relative to the amount of resources necessary to achieve that

> promise, and what is a reasonable timeframe for achieving program performance goals.[21]

The American Medical Association ("AMA") has not, by any means, endorsed the concept of pay-for-performance programs, particularly because of the budget-neutral aspect of such programs for governmental patients. At its June 2005 Annual Meeting, the AMA House of Delegates adopted a resolution regarding P4P programs that includes the following principles:

- Ensure quality of care.
- Foster the relationship between patient and physician.
- Offer voluntary physician participation.
- Use accurate data and fair reporting.
- Provide fair and equitable program incentives.[22]

The AMA continues to be concerned about the myriad of measurements being proposed under private and governmental P4P programs, the cost to physician practices to operate under such programs (particularly the necessary investment in information technology), and the potential for such programs to interfere with the patient-physician relationship.[23]

III. HOSPITAL/PHYSICIAN ALIGNMENT STRATEGIES

It is evident that the P4P initiatives are going to intensify at the payer level. For any health care system to be successful under this type of reimbursement system, it must have a coordinated approach to the delivery of health care services. These efforts must involve the hospital medical staff. This realization is neither revolutionary nor novel. However, for a number of reasons (a lack of aligned incentives being one of the greatest), efforts to coordinate care around improved quality, patient safety, and efficiency have fallen short of their potential. Increasingly, hospitals and their affiliated physicians are embarking on a number of alignment strategies aimed at these goals. Motivations vary—financial, competitive, market share, reputation—but one key driver of these alignment efforts is to prepare the health system for payment based increasingly on objective measures of performance. Among others, these hospital/physician alignment strategies include ancillary service joint ventures, clinical service line management arrangements, participating bond transactions, gainsharing, clinical integration, and physician employment. While none of these strategies is necessarily new,

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21. *Id.*

22. AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES, *Pay for Performance Initiatives and Physicians Who Serve Minority Patient Populations*, Res. 218 (A-05) (May 11, 2005).

23. *Id.*

what is encouraging is that the financial incentives associated with each is being increasingly focused on quality outcomes, patient safety, and efficiency supported significantly by the deployment of cutting-edge information technology. No one size fits all and what works in one institution may not work in another. But those hospitals and physicians who accept the status quo may lose out on the benefits a P4P system can yield.

The goals of any hospital/physician alignment strategy will vary, but they can be fairly summarized as follows:

- To create an opportunity for the physicians to be more involved in the control, governance, management, and overall decision-making processes with regard to both the operational and clinical aspects of a particular clinical service line.
- To align clinical, operational, and financial incentives among the physicians, the hospital, and other caregivers.
- To focus on those processes of care that have the greatest impact on quality, patient safety, and efficiency.
- To distinguish the providers in the marketplace.
- To obtain measurable and objective improvements in quality, patient safety, and efficiency.
- To facilitate the acquisition and deployment of information systems that support the goals of the alignment strategy.

Several alignment strategies designed to accomplish these goals are discussed in brief below.

A. Participating Bond Transactions

Unlike traditional fixed-interest, tax-exempt bonds, Participating Bond Transactions ("PBTs") involve the sale of participating instruments. This means that the bondholders share in the success or failure of the venture financed by the participating bonds. Some of these bonds are sold to physicians associated with the venture, while others are sold to institutional investors. For example, a hospital may issue participating bonds to partially finance the construction of a new imaging center or ambulatory surgery center ("ASC"). A portion of these bonds would be made available for purchase by members of the hospital's medical staff that meet certain pre-established criteria unrelated to the volume or value of referrals the physicians may make to the new venture. The rest of the bonds would be sold on the open market. The participating bonds would pay the investors based on the economic performance of the imaging center or ASC. If performance is poor in a given

year, holders of participating bonds might receive little or no interest for that year. On the other hand, if the venture performs well (i.e., to the pre-established financial targets), interest is paid to the bondholders. Thus, the bondholders are motivated to ensure the success of the venture.

Participating bonds are often subordinated obligations, meaning that the participating bondholders will not be paid until all obligations have been met to the senior bondholders. As a result of the subordinated nature of the bonds and the risk that the venture will not meet the pre-established financial standards, the interest rate on participating bonds is generally higher than that available on traditional fixed-interest bonds. These rates can be in the range of twelve percent to fifteen percent on a tax-free basis.[24]

Germane to P4P principles, participating bond transactions can be structured in a manner such that the triggers pertaining to the payment of interest on the bonds go beyond those that are economic in nature to those that relate to the quality of care and/or efficiency of a particular service. In the context of an ASC, these triggers could include patient satisfaction, on-time starts, infection rates, medication errors, returns to surgery, and other similar measures. Accordingly, the physician bondholders who also use or refer patients to the center are incentivized to achieve not only economic results, but also results related to quality or efficiency in order to ensure the payment of interest on the bonds.

B. Clinical Integration

Clinical integration is a concept arising out of the application of the antitrust laws to provider networks and their contracting activities. Federal and state antitrust laws have long recognized financial integration as a means for health care providers to engage in joint negotiations over prices with health plans without being condemned as *per se* illegal horizontal price-fixing.[25] Financial integration can be achieved in a number of ways, including merger, substantial risk-sharing, and other means that create a "unity of interest" among the participants in the integration efforts.[26] According to certain *Joint Policy Statements* issued by the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"), sufficiently clinically integrated physician networks for antitrust purposes are treated in the same fashion as financially integrated networks.[27]

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24. Thomas Ryan & Robert Rosenfield, *Special Report: A "Carrot" and "Stick" Approach To Improve Physician-Hospital Relations*, GOVERNANCE INST. 7 (2003).

25. *See generally Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Healthcare*, WASH. REG. REPORTING ASSOCIATES, Aug. 28 1996 [hereinafter FTC].

26. Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 771 (1984).

27. FTC, *supra* note 25, at statement 8.

Specifically, Statement Eight of the *Policy Statements* explains that sufficient clinical integration, absent economic risk-sharing, "can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."[28] The Statement goes on to state that such a program may include:

- establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care;
- selectively choosing network physicians who are likely to further these efficiency objectives; and
- the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.[29]

Clinically integrating a group of otherwise independent physicians or other health care providers to the degree sufficient to pass muster under the antitrust laws is no easy matter. To date, the FTC has issued only one advisory opinion approving a proposed clinical integration model.[30] Even so, while the ability to jointly negotiate managed care contracts is one benefit of a fully clinically integrated model, networks falling short of this degree of integration can still follow the FTC or the DOJ's guidance in an effort to better coordinate care and control quality, without necessarily jointly negotiating payer contracts. In other words, the underlying concepts of clinical integration dovetail nicely with those of the pay-for-performance movement and are responsive to the health care market.

Hospitals and health systems may be able to play a significant role in encouraging and facilitating clinical integration among their physicians and other affiliated providers. These efforts may include education, information technology support, care management staff, data collection and analysis, clinical protocol development, electronic medical record, credentialing, consulting, and legal support.

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28. *Id.*; *see also* Robert F. Leibenluft & Tracy E. Weir, Clinical Integration: Assessing the Antitrust Issues (Feb. 8, 2006) (unpublished conference held by Physicians and Physician Organizations Law Institute).

29. Leibenluft & Weir, *supra* note 25, at 9.

30. *See* Letter from Jeffrey W. Brennan, Assistant Dir. Health Care Servs. & Prods., FTC, to John J. Miles, Principal at Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), *at* http://www.ftc.gov/bc/adops/medsouth.htm (last visited Mar. 25, 2006).

C. Employment

In the late eighties and early nineties, there was significant activity among hospitals, health systems, and physician practice management companies ("PPMs") with regard to the acquisition of physician practices, predominantly primary care practices. Here, the hospital, health system or PPM would acquire all, or substantially all, of the tangible and intangible assets of the practice, and subsequently enter into employment agreements with the selling physicians. These transactions were largely in response to the managed care movement occurring at the time. Common wisdom held that those health care systems with the largest number of primary care doctors available to serve as gatekeepers and managers of care would be the most attractive to managed care companies looking for a network that could either provide health care services on a capitated or some other risk-sharing basis.

A number of lessons have been learned with regard to the physician employment model, particularly the importance of productivity-driven compensation systems and the recognition that administrators do not make clinical decisions, rather physicians do. Also, risk-based contracting, particularly fully capitated arrangements, has not gained the market prevalence first predicted. Nonetheless, the employment model continues to be effective today for a number of hospitals as a means to integrate hospital and physician services, including the increased prevalence of the employment of specialty physicians.

As the employer, hospitals may have increased flexibility with regard to implementing and incentivizing certain quality and efficiency standards among its employed physicians, such as the adoption of clinical protocols and other common processes across the continuum of care. The employment contract can be used to require and incentivize physicians to coordinate and manage care processes in accordance with those pay-for-performance standards incorporated into the payer contracts held by the hospital. Also, financing the acquisition and deployment of useful technologies may be more easily achieved under an employment model as compared to implementing these initiatives among a disparate group of independent physicians.

D. Ancillary Service Joint Ventures

Ancillary service joint ventures can take a number of forms and encompass a variety of services. Historically, joint ventures between hospitals and doctors focused on outpatient services, such as imaging and diagnostic centers, cardiac catheterization laboratories, ambulatory surgery centers, and the like. Recently, there has been a proliferation of joint ventures aimed at the

joint ownership of licensed hospitals, particularly specialty hospitals (e.g., heart and orthopedic hospitals).[31]

The benefits of hospital/physician ancillary service joint ventures can be significant. Through an affiliation with physicians, the hospital secures the opportunity to expand its services in high-growth areas and also increases collaboration and trust with its physician-partners. Similarly, these joint ventures give physicians the opportunity to diversify their income streams and to gain more significant control over both the operational and clinical aspects of the joint-ventured service. It is this latter benefit that provides an opportunity to align economic incentives around the pay-for-performance principles of quality, patient satisfaction, and patient safety. To the degree the financial success of the joint venture is tied to certain quality, efficiency, or patient safety standards, the more vested the physician-owners will be in ensuring that these standards are met.

E. Clinical Service Line Management Arrangements

This model entails the management of a hospital's entire clinical service line by a particular group of physicians or a new company jointly owned by the hospital and certain physicians formed for that purpose. The underlying concept is the delegation to the physician-managers of significantly more authority with respect to both the operational and clinical aspects of the service line, particularly those aspects that the physicians can control or significantly influence.

The principal elements of a service line management arrangement are as follows:

- An independent analysis is conducted of a particular clinical service line of the hospital to identify areas of improvement in terms of clinical inputs, clinical outcomes, patient safety, efficiencies, information technology, and patient satisfaction.
- The hospital and physicians' current performance with regard to these areas are benchmarked against local, regional, and national statistics to identify the range of improvement opportunities.
- Specific areas of improvement that are measurable, objective, and largely under the control of the

31. A regulatory exception exists under the Stark Statute, commonly referred to as the "Whole Hospital Exception." 42 C.F.R. § 411.356(c)(3) (2006). This exception permits a physician with an ownership interest in a hospital to make referrals to that particular hospital providing the referring physician is authorized to perform services at the hospital. *Id.* However, the physician's ownership or investment interest must be in the hospital as a whole and not merely in a distinct part or department of the hospital. *Id.*

physicians are identified and agreed upon as the areas of focus. These standards may be related to P4P measurements contained in particular payer contracts or related solely to hospital-specific goals with respect to quality and efficiency improvements.

- A management services or performance improvement agreement is entered into between the hospital and a particular physician specialty group or the joint-ventured management company. This agreement sets forth in detail the management obligations and performance standards expected.
- Compensation is structured based on a combination of a base management fee for general service line management services, and incentive compensation tied to the targeted performance standards.
- An independent valuation firm is engaged to opine as to the fair market value range of the compensation for the scope of services to be provided, including the general management services and the performance standards.
- The company is operationalized and performance standards are reviewed and revised periodically over the term of the arrangement.

The service line management model creates an effective forum for hospitals and physicians to work together to improve care based on agreed upon objective measures of performance with the added benefit of a financial upside for positive improvement. These attributes are responsive to underlying principles of P4P programs.

F. Gainsharing

Gainsharing is a concept that has garnered a lot of attention lately as a means of aligning hospital and physician incentives around cost-savings. Generally, gainsharing programs provide payments to physicians of a portion of the hospital's cost-savings resulting from the physicians' efforts in changing care processes, reducing waste, increasing efficiencies, and/or standardizing supplies. These types of programs have been popular with regard to high-cost service lines, such as cardiac and vascular care, orthopedics, and oncology. For example, a hospital could design a gainsharing program around the standardization of the number and variety of drug eluting stents used in cardiac surgery. To the extent such standardization results in a cost-savings to the hospital as measured against a baseline, a portion of such cost-savings would be paid directly to those physicians that participated in the standardization process. The Inspector General of the Department of Health

and Human Services ("OIG") has long been concerned that these types of programs may adversely affect the care provided to Medicare beneficiaries.

The OIG issued a Special Advisory Bulletin in July 1999 that stated that certain hospital/physician gainsharing arrangements violate the Civil Monetary Penalties Law ("CMP") by improperly inducing physicians to reduce the level of care provided to patients.[32] According to the OIG, such arrangements marketed only to physicians in a position to refer patients may induce investor-physicians to limit patient services. This incentive is created by permitting the physician a percentage of profits generated by cost savings in clinical care and thus could violate the CMP "in at least some circumstances" and may implicate the federal Anti-Kickback Statute.[33] More specifically, the OIG stated that "any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute." Adding later in that same Special Advisory Bulletin, the CMP "prohibits any hospital-physician incentive plan that compensates a physician directly or indirectly based on cost savings on items and services furnished to patients under the physician's clinical care."[34] However, the OIG noted the following:

> [h]ospitals may align incentives with physicians to achieve cost savings through means that do not violate [the CMP]. For example, hospitals and physicians may enter into personal services contracts where hospitals pay physicians based on a fixed fee that is fair market value for services rendered, rather than a percentage of cost savings. Such contracts must meet the requirements of the anti-kickback statute.[35]

In an about-face, the OIG formally approved a hospital cost-saving program in January 2001 that compensated cardiac surgeons for certain supply cost savings.[36] Also, in February 2005, the OIG approved six similar cost-savings programs related to hospitals' cardiac surgery and cardiology programs.[37] Even though the OIG believed these programs might incentivize the limitation or reduction of services to beneficiaries, it found enough

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32. DEP'T HEALTH AND HUM. SERVS., OIG, Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (1999).

33. *Id.* at Section B.

34. *Id.* at Section D.

35. *Id.*

36. OIG, DEP'T HEALTH & HUM. SERVS., Advisory Opinion No. 01-01 (2001), *available at* http://oig.hhs.gov/fraud/advisoryopinions.html (last visited Mar. 25, 2006).

37. OIG, DEP'T HEALTH & HUM. SERVS., Advisory Opinion No. 05-01 (2005), 05-02 (2005), 05-03 (2005), 05-04 (2005), 05-05 (2005), and 05-06 (2005), *available at* http://oig.hhs.gov/fraud/advisoryopinions.html (last visited Mar. 25, 2006).

safeguards to approve the programs for those providers seeking the OIG's opinion. Thus, the OIG will look to the operation of the program to determine whether or not it violates the terms of the statute.[38]

MedPAC recently released a draft recommendation to Congress that, among other things, addressed gainsharing arrangements between physicians and hospitals.[39] MedPAC stated that it believes that gainsharing could better align hospital and physician financial incentives and could be structured to have fewer risks than outright physician ownership of hospitals. While MedPAC acknowledged concerns with gainsharing, including the OIG's concerns that gainsharing arrangements could violate the CMP, it indicated that HHS could be provided the statutory authority to develop protections to ensure that gainsharing arrangements do not harm the quality of patient care, while at the same time aligning financial incentives.[40]

Finally, the Deficit Reduction Act of 2005 contains a provision authorizing a gainsharing demonstration project.[41] This provision requires the Secretary to approve gainsharing demonstration projects by November 1, 2006. The Secretary would be required to test and evaluate methodologies and arrangements between hospitals and physicians. Gainsharing was originally designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of remuneration as specified in the project. The Secretary is to approve not more than six of these projects, at least two of which must be located in rural areas.[42]

By their nature, gainsharing programs are focused almost entirely on cost-savings, not quality or efficiencies; although cost, quality and efficiencies are not necessarily mutually exclusive. As such, the responsiveness of these types of programs to P4P principles is debatable; but success in incentivizing savings for the hospital is still significant.

IV. LEGAL CONSIDERATIONS

There exists a labyrinth of state and federal laws that impact the ability of hospitals and physicians to align incentives around pay-for-performance principles. Economic relationships among providers of care in positions to refer patients to one another are heavily regulated. State and federal

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38. *MedPAC Report to Congress: Medicare Payment Policy: Hearing Before the Subcomm. on Health Comm. on Ways and Means, U.S. House of Representatives* (Oct. 7, 2005) (statement of Lewis Morris, Chief Counsel to the Inspector Gen., Dep't Health & Hum. Servs.) (on file with author).

39. MEDPAC REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 183-90 (2005).

40. *Id.*

41. Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5007 (2006).

42. *Id.*

governments are concerned that these types of relationships can corrupt sound medical judgment and subordinate patients' best interests to the providers' economic interest.

A review of each federal and state law and regulation applicable to hospital/physician alignment strategies is beyond the scope of this article. However, a brief analysis of several of the more pertinent federal laws impacting economic relationships among hospitals and physicians is instructive as one tries to navigate the murky waters of hospital-physician relationships.

A. Civil Monetary Penalties Law

The federal Civil Monetary Penalties Law ("CMP") prohibits a health care provider from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to Medicare or Medicaid patients under the physician's direct care.[43] Violations of the CMP can result in civil monetary penalties of $2,000 per patient against both the hospital and the physician.[44] This statute is broadly written and does not distinguish financial incentives to limit medically *necessary* services from financial incentives to limit medically *unnecessary* services. Thus, by a literal interpretation of the statute, hospitals are prohibited from incentivizing physicians financially to reduce waste, excessive lengths of stay, or overutilization of supplies or services. This seemingly contradictory prohibition is a large impediment for any hospital that is trying to respond to the federal government's mantra of increased quality and decreased costs.

As stated above, it is the CMP that prohibits gainsharing programs since such programs, on their face, are attempts to generate cost-savings through the reduction of a service or supply. The CMP prohibits such cost-saving efforts even where the service or supply is unnecessary, wasteful, or ineffective. The OIG has acknowledged this result; but until Congress chooses to amend the CMP Law, the ability for hospitals to incentivize their physicians financially to reduce waste may be limited.

B. Anti-Kickback Statute

The federal Anti-Kickback Statute makes it a felony to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program.[45] Violation of these provisions may result in imprisonment for up to five years and fines of up to $250,000 in the case of individuals, and

43. 42 U.S.C. § 1320a(b) (2006).
44. *Id.*
45. 42 U.S.C. § 1320a-7b(b) (2006).

$500,000 in the case of organizations.[46] Convictions under the Anti-Kickback Statute result in mandatory exclusion from federal health care programs for a minimum of five years. In addition, the Department of Health and Human Services has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from the federal health care programs for not less than five years.[47] Generally, courts broadly interpret the scope of the Anti-Kickback Statute, holding that the statute may be violated if merely *one purpose* of a payment arrangement is to induce referrals.[48]

Congress has required that the Department of Health and Human Services issue regulations establishing a number of "safe harbors" under the Anti-Kickback Statute. These regulations would include payment practices in the health care industry, which practices will not be treated as violations of the Anti-Kickback Statute, or provide the basis for exclusion from federal health care programs.[49] An arrangement must fully comply with each and every element of an applicable safe harbor in order to qualify for protection.[50] However, the mere failure of an arrangement to qualify for safe harbor protection does not mean that the arrangement violates the Anti-Kickback Statute; it simply means that such arrangement will be reviewed within the context of the statute to determine if the requisite intent is present to pay or receive remuneration in exchange for referrals.[51]

The Anti-Kickback Statute is not generally applicable to P4P programs between providers and payers since there is no referral relationship between these parties. The Anti-Kickback Statute, however, is implicated within the context of many hospital/physician alignment strategies on two levels. First, many alignment strategies result in a flow of funds from the hospital to the physicians participating in the strategy, the same physicians that are referral sources for the hospital. The government is suspicious that such payments are merely disguised payments for referrals, not for quality improvement, efficiencies, or other objectives of the alignment model.[52] Secondly, many alignment strategies involve the formation of a new company owned jointly by the hospital and the participating physicians. The investment interests held by the hospital and the physicians in these companies and the resultant

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46. *Id.*

47. *Id.*

48. *See* United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

49. 42 C.F.R. § 1001.952 (2005).

50. *Id.*

51. *See* 61 Fed. Reg. 2,122, 2,124 (Jan. 25, 1996) (to be codified at 42 C.F.R. pt. 1001); *see also* OIG, DEP'T HEALTH & HUM. SERVS., Advisory Opinion No. 04-19 (2004), for a representative explanation by the Office of the Inspector General stating that facts and circumstances are evaluated when an arrangement does not qualify for safe harbor protection.

52. Supplemental Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005); *see also* OIG, Dep't. Health & Hum. Servs. Special Advisory Bulletin, Contractual Joint Ventures (April 2003).

distributions create another level of remuneration among referral sources that is governed by the Anti-Kickback Statute.

A participant in a hospital/physician alignment strategy (or other relationships among referral sources involving remuneration of any kind) may request an opinion of the OIG as to whether the OIG would pursue a prosecution of the arrangement as a result of its failure to meet each and every element of the applicable safe harbors.[53] Such an advisory opinion is the only sure way to protect arrangements that are not otherwise afforded safe harbor protection.

C. Stark Law

The federal Stark Law prohibits a physician who has a financial relationship with an entity (including hospitals) that provides "designated health services" from referring federal health care program patients to such entity for the furnishing of such services, with limited exceptions.[54] The Stark Law also prohibits the entity receiving the referral from filing a claim or billing for the services arising out of the prohibited referral. The prohibition applies regardless of the reasons for the financial relationship and the referral; that is, unlike the federal Anti-Kickback Statute, no finding of intent to violate the law is required. Sanctions for violation of the Stark Law include denial of payment for the services provided in violation of the prohibition, refunds of amounts collected in violations, a civil penalty of up to $15,000 for each service arising out of the prohibited referral, exclusion from the federal health care programs, and a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition.[55] Regulations under the Stark Law provide for certain relationships that are excepted from the Stark Law's prohibitions.[56] Again, similar to the Anti-Kickback Statute, the Stark Statute generally will not affect P4P arrangements between providers and payers since the providers do not refer "designated health services" to payers. Such services most often are referred to hospitals or other ancillary providers, such as imaging centers or home health agencies. As such, the Stark Statute often will be implicated in hospital/physician alignment strategies due to the referral relationship between the parties coupled with the financial relationship created by most alignment arrangements. Importantly, a prerequisite to any such alignment strategy is the existence of an exception under the Stark Statute that will ensure compliance with this civil statute.

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53. 42 C.F.R. § 411.370(b) (2006).
54. 42 U.S.C. § 1395nn (2006).
55. 42 U.S.C. §§ 1395nn(g)(3), (4) (2006).
56. 42 C.F.R. § 411.354 (2006), *et seq.*

D. Internal Revenue Considerations

To qualify for exemption under Internal Revenue Code Section 501(c)(3), an organization must be organized and operated exclusively for religious, charitable, scientific or educational purposes.[57] The "promotion of health" has long been recognized as a charitable purpose so long as it is for the benefit of the community as a whole.[58] To satisfy the organizational test, the organization's governing documents must:

> (i) limit the organization's purposes to one or more exempt purposes; (ii) not expressly empower the organization to engage in nonexempt activities; (iii) provide that, upon dissolution, assets will be distributed for one or more exempt purposes; and (iv) not empower the organization to devote more than an "insubstantial" amount of activities to engage in activities which, in themselves, are not in furtherance of the organization's exempt purposes (including, for example, influencing legislation or participating in political campaigns).[59]

To satisfy the operational test, the organization must be operated exclusively for one or more exempt purposes, *i.e.*, it must engage primarily in activities that further its tax-exempt purpose or purposes.[60] For federal income tax purposes, the IRS has ruled that the activities of a partnership should be considered the activities of the partner.[61] The IRS has taken the position that this approach also applies for purposes of the operational test of exemption.[62] Thus, the activities of a joint venture that is structured as either a partnership or as an LLC that is treated as a partnership for federal income tax purposes also will be considered to be the activities of the joint venture's tax-exempt participants.

Code Section 501(c)(3) also requires that no part of the exempt organization's net earnings inure to the benefit of any private shareholder or individual.[63] There is no *de minimis* exception to the proscription against private inurement. If any private inurement is found, exemption will be revoked.[64] The term "private shareholder or individual" refers to persons

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57. I.R.C. § 501(c)(3) (2006).
58. *See* Rev. Rul. 69-545, 1969 C.B. 117.
59. Treas. Reg. § 1.501(c)(3)-1(b) (1959).
60. Treas. Reg. § 1.501(c)(3)-1(c)(1), § 1.501(c)(3)-1(d)(ii) (1959).
61. *See* Butler v. Comm'r, 36 T.C. 1097 (1960); Rev. Rul. 98-15, 1998-1 C.B. 718.
62. *Id.*
63. Treas. Reg. § 1.501(c)(3)-1(c)(2) (1959).
64. *See, e.g.*, McGahen v. Comm'r, 76 T.C. 468, 482 (1981); Spokane Motorcycle Club v. United States, 222 F. Supp. 151 (E.D. Wash. 1963).

having a personal and private interest in the activities of the organization.[65] IRS rulings and case law apply the private inurement proscription *only* to "insiders," defined to include a person receiving a benefit as a result of his, her, or its control or influence over the tax-exempt entity, such as shareholders, founders, directors, officers, or major contributors.[66] Whether a physician is an insider depends on an analysis of all the facts and circumstances concerning whether the physician's relationship with the organization offers the physician the opportunity to make use of the organization's income or assets for personal gain.[67]

In 1996, Congress enacted the "Taxpayer Bill of Rights 2" which, among other things, imposed a series of penalty excise taxes in "excess benefit transactions" where exempt organizations: (i) pay unreasonable compensation to individuals that are in a position to substantially influence the organization; (ii) pay compensation based in whole or in part on the revenues of the organization in a manner that results in private inurement; or (iii) enter into arrangements that result in the payment of more for assets than such assets are worth or selling assets for less than they are worth. These provisions, which are commonly referred to as the "Intermediate Sanctions Law," are effective for transactions occurring on or after September 14, 1995.[68] In January 2002, the IRS issued final regulations closely following the temporary regulations. These final regulations have significant implications for tax-exempt organizations, and in particular, health care providers, as they provide amplification and clarification of the provisions of Code Section 4958.[69]

Tax-exempt hospitals that engage in physician alignment strategies will need to ensure that such strategies are consistent with their charitable purpose and that no more than fair market value is paid to physicians as part of any incentive program. With proper structuring, these objectives can be accomplished.

V. CONCLUSION

Pay-for-performance programs are aimed at revising a reimbursement system based on the number and complexity of services provided, to one based on objective measures of quality and efficiency. The debate will rage on, and time will tell, as to whether a P4P system will gain true traction in the health services marketplace and, more importantly, whether it will yield measurable improvements in quality of care. Those hospitals and health systems that use this time to align incentives with their physicians around

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65. Treas. Reg. § 1.501(a)-1(c) (1959).

66. Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii) (1959).

67. *See generally* Lawrence M. Brauer & Charles F. Kaiser III, *Physician Incentive Compensation*, I.R.S. CPE MATERIALS FOR FY 2000 (July 1999).

68. I.R.C. § 4958 (2006).

69. *Id.*

quality, patient safety, efficiency, and deployment of technology will gain a strategic advantage in the marketplace and may even achieve significant progress toward a more rational system of health care delivery.