

Chapter 5

In Common Cause for Quality

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I. INTRODUCTION

§ 5:1 Generally

The things that unite us are more important than the things that divide us.

—John Gardner in 1970 founding “Common Cause”

The need to improve the quality of American health care has been a largely unfulfilled, persistent policy cry for at least the last thirty years.¹ Market forces have not worked. Reimbursement and payment policies have, in the main, failed to generate enough change. Regulation has primarily added to the problem rather than cured it.²

Frustration with the pace and breadth of improvement has spawned a plethora of initiatives to measure, analyze, incentivize, improve, report, pay for and criticize the status quo. A whole industry in creation of the infrastructure to facilitate these efforts has developed—from software develop-

[Section 5:1]

¹Gosfield, “Contracting for Provider Quality: Then, Now and P4P,” *Health Law Handbook* (A. Gosfield, ed. 2004).

²Gosfield, “Making Quality Happen: In Search of Legal Weightlessness,” *Health Law Handbook* (A. Gosfield, ed. 2002).

ers,³ to guidelines authors,⁴ measurement and report card programs,⁵ efficiency measurement techniques,⁶ disease management companies,⁷ and a vast array of information technology applications and hardware. Consultants to facilitate implementation of and compliance with these efforts proliferate. Yet the goals remain elusive. What is the problem?

While there are undoubtedly a host of explanations for the inadequate results of the efforts expended over these decades, one which has been little explored is the loss of a sense of common purpose among the principal drivers of health care. Physicians, hospitals and managed care plans which determine the health care patients get unfortunately are more frequently referred to these days as “stakeholders”—as if their interests, their stakes, in the health care system are disparate and competing. Most significantly and more dramatically, the shifting values and tensions among and between physicians on one side and their significant others in health care—hospitals and managed care plans—on the other side, causes them all to focus more on where their business needs are in conflict rather than in concert. All of this has been essentially counterproductive to the quality improvement mission.

Rampant mythologies about the impact of the fraud and abuse laws have perpetuated lagging accomplishment; and sometimes have been used, even disingenuously, as an excuse to avoid working together. The antitrust laws have been lamented as obstacles to quality improvement because they do not let competitors engage in anticompetitive

³This includes the government itself in CONQUEST and Q-SPAN (<http://www.ahrq.gov/qual/qspanovr.htm>), to commercial vendors selling software to generate HEDIS measures (<http://www.ncqa.org/communications/news/softwareocto5.htm>) to a host of other applications and vendors.

⁴See <http://www.guideline.gov> for a host of guidelines sponsored by diverse entities.

⁵See Gosfield, “Health Care Report Cards: Quality in the Public’s Cross Hairs,” *Health Law Handbook* (A. Gosfield, ed. 2000).

⁶See “Episode Treatment Groups,” http://www.symmetry-health.com/ETGTut_Desc1.htm and Farthenson, Dove and Wooster, “Episode Treatment Groups (ETGs): A Patient Classification System for Monitoring Outcomes Performance by Episode of Illness,” 21 *Topics in Health Information Mgt.* 21 (2000).

⁷See “DM Directory,” <http://www.dmaa.org/dmdirectory/queryall.asp>.

behavior. The time has come to debunk these myths and shine a bright light on ways in which the business case for quality among this critical triumvirate is both complementary and consistent, and likely will be propelled through more collaboration and less fractionation.

This chapter: (1) examines where the pressures for collaboration can be found; (2) elucidates how the natural interdependency for quality, between physicians and hospitals on one hand and physicians and plans on the other, can be marshaled effectively for change; (3) explains how to successfully navigate the legal minefields; and (4) offers some specific programmatic initiatives to jumpstart a faster journey to the goal—better quality of care drawing on the marvels of a system of people and institutions that can simply do better at this.

§ 5:2 Where do the pressures for collaboration arise?

With the publication of “To Err is Human”¹ and “Crossing the Quality Chasm,”² and promulgation of its STEEEP³ values, the national sense of common quality aims was heightened. This perception accelerated with the explicit adoption of these values and concerns by the Leapfrog Group,⁴ Bridges to Excellence,⁵ the National Quality Forum,⁶ the National Patient Safety Foundation,⁷ and the Institute for Healthcare Improvement (“IHI”)⁸ among others—all programs created to propel quality improvement in health care faster than its natural incremental tendencies.

One of the core values within the “patient-centeredness” of the STEEEP aims is transparency of far more in health care,

[Section 5:2]

¹Kohn et al., “To Err is Human” (National Academy Press 1999).

²Corrigan et al., “Crossing The Quality Chasm” (National Academy Press 2002).

³Care should be safe, timely, effective, efficient, equitable, and patient-centered.

⁴<http://www.leapfroggroup.com>.

⁵<http://www.bridgestoexcellence.org/bte/bte-overview.htm>.

⁶<http://www.qualityforum.org>.

⁷<http://www.npsf.org>.

⁸<http://www.ihl.org>.

but most particularly of quality performance. The theory is that by making available more information about health care performance and payment, the entire system will be rendered more accountable for its performance and will, therefore, improve. While there has been a longstanding hope that an increase in the types of and utility of health care data will foster a better informed, activated health care consumer population, there has been little evidence to date that consumers actually use report cards and make their health care purchasing decisions based upon them.⁹ Some argue that this is because the information made available is not really meaningful or useful; others argue that this relatively weak effect reflects the severe market distortion in health care, because consumers are shielded from real purchasing decisions by first or early dollar coverage of their health care costs by employer-based or government provided health insurance. Still further, with restricted managed care networks, the argument goes, patients go where their physician sends them and their plan covers them. Even so, there is other data that demonstrates that even when consumers do not alter *their* behavior in response to published data, those reported upon actually do improve their performance.¹⁰

Not only to bolster transparency but also because “what gets measured gets done,”¹¹ a virtual hurricane of performance measurement initiatives is storming the land of health care.¹² The Agency for Healthcare Research and Quality (“AHRQ”) sponsored performance measures clearinghouse now has more than 730 measures available and these are on a limited range of conditions.¹³ The mere fact of performance measurement changes the behavior of those who are its

⁹See Gosfield, “Health Care Report Cards: Quality in the Public’s Cross Hairs,” *Health Law Handbook* (A. Gosfield, ed. 2000).

¹⁰Chassin, “Achieving and Sustaining Improved Quality: Lessons From New York State and Cardiac Surgery,” *Health Affairs* 40-50 (July/Aug 2002).

¹¹McGlynn, “Six Challenges in Measuring the Quality of Health Care,” *Health Affairs*, 7-21 (May/ June 1997).

¹²Gosfield, “The Performance Measures Ball: Too Many Tunes, Too Many Dancers?,” *Health Law Handbook* (A. Gosfield, ed. 2005).

¹³<http://www.qualitymeasures.ahrq.gov/about/contentoverview.aspx>.

subjects.¹⁴ Although early measurement was focused primarily around hospital care, that is changing with increased measurement of physicians, other ambulatory care providers, nursing homes, home health agencies and more.

Measures are used in ways that will significantly affect physicians, hospitals and plans, from pay for performance which will give them more revenues, to rankings as best health plans¹⁵ and best hospitals.¹⁶ Physicians who are acknowledged as diabetes certified providers in the Bridges to Excellence program have gotten more patients to treat than non-certified physicians and they are caring for them at lower cost.¹⁷ Hospitals and physicians who are measured as most efficient increasingly get the opportunity to participate in more exclusive networks¹⁸ than has been the case for the last fifteen years, during which time full access to all providers in a market characterized most health plans. Similarly, where plans “tier” their networks¹⁹ based on performance measures of various kinds, the intention is to motivate consumers to go to the most efficient providers by charging them far higher co-payments for the less efficient providers. The point is that performance measurement means that those who score well will be more successful getting higher payment, increased consumer attention and better branding opportunities.

In managed care, these effects have had a longer history

¹⁴See Chassin, “Achieving and Sustaining Improved Quality: Lessons From New York State and Cardiac Surgery,” *Health Affairs* 40-50 (July/Aug 2002).

¹⁵Press Release, “NCQA, US News and World Report to Collaborate on America’s Best Health Plans” (Sept 12, 2005) <http://www.ncqa.org/Communications/News/USNews.htm>.

¹⁶US News and World Report, “America’s Best Hospitals 2005,” <http://www.usnews.com/usnews/health/best-hospitals/tophosp.htm>; Solucient, “Top Performing Cardiovascular Hospitals Save Thousand More Patients Each Year,” <http://www.100tophospitals.com>.

¹⁷Ingenix, “Diabetes Program Evaluation 2005” http://www.bridgestoexcellence.org/bte/pdf/DRRP_Eval_2005.pdf.

¹⁸See, e.g., reports of Aetna and United networks in “Innovative Products Offer Narrow Provider Networks Targeted to High Cost Diseases,” *Managed Care Week* (Oct. 6, 2003), at <http://www.aishealth.com/ManagedCare/DM/MCWInnovativeProdds.html>.

¹⁹See Terry, “What ‘tiered networks’ will mean to you,” *Medical Economics* (Sept. 17, 2004), <http://www.memag.co/memag/article/articleDetail.jsp?id=123434>.

through the application of accreditation, particularly by the National Committee for Quality Assurance (“NCQA”), as a threshold for an employer to even offer a plan. HEDIS data, which originally began as a way for employers and health plans to have a common basis on which to compare plan performance,²⁰ is now embedded in the accreditation decision and provides the basis for a national report card which ranks health plans and, still further, serves as the foundation for an annual report on the state of health care quality in the managed care arena.²¹

In parallel with this heightened market oriented approach to quality performance is a far greater emphasis on patient safety. The Leapfrog Group asks hospitals to report on the extent to which they have implemented three specific safety initiatives including using only intensivists in the ICU, implementation of computerized physician order entry (“CPOE”) and meeting baseline performance measures for centers of excellence for specified clinical treatments.²² Purchasers are expected to use this data in deciding which hospitals they will make available to their employees and retirees.

A different force driving toward safety is the “100,000 Lives Campaign” launched in late 2004 by the IHI to shove hospitals toward implementing six specific health care delivery techniques (the “planks” of the campaign).²³ By six months after its announcement, more than 2,800 organizations had enrolled as committing to adopt the planks. There is a strong argument that by virtue of the campaign itself, the malpractice standard of care for hospitals was changed overnight.²⁴ As a result, the risks to hospitals who do not implement the six planks, whether they enrolled in the campaign or not, are on a steep incline, creating something

²⁰Gosfield, “Guide To Key Legal Aspects In Managed Care Quality” (Faulkner and Gray, New York, 1996).

²¹NCQA, “The State of Health Care Quality 2005,” http://www.ncqa.org/Docs/SOHCQ_2005.pdf.

²²“The Leapfrog Group Fact Sheet,” http://www.leapfroggroup.org/about_us/leapfrog-factsheet.

²³<http://www.ihl.org>.

²⁴Gosfield and Reinertsen, “The 100,000 Lives Campaign: Crystallizing Standards of Care for Hospitals,” *Health Affairs* 1560-70 (Nov./Dec. 2005).

almost more compelling than a market imperative. It is inevitable that malpractice cases will be brought to recompense patients for deaths and injuries which would have been avoided by implementation of the campaign planks.

§ 5:3 What is the business case for quality?

Many providers and health plans have argued that to really ratchet up the quality in their services costs money and the employers and government who are paying the freight are unwilling to pay more for what it costs to make quality happen. In response, there are certainly moral arguments that the obligation to provide health care services with high scientific quality in the context of a true healing relationship is an inherent obligation of health care providers; so that paying more to do that which should be done anyway is inappropriate. Still, however, the issue as to whether, from a business perspective, the parties one might seek to motivate will be so motivated turns on whether there is a business case for them to respond to incentives. To propel quality more effectively, to understand whether the business interests of physicians on one hand and hospitals and health plans on the other are in conflict, it is important to elucidate what a business case would be.

Some have proposed that a business case for quality turns on two principles: (1) Does the investing entity realize a financial return in a reasonable time frame, whether actual profit, reduced losses, or avoided costs? and (2) Does the entity believe there is a positive indirect effect on organizational function and sustainability will accrue within a reasonable time?¹ This characterization is really no more than a return on investment analysis. Still further it focuses on a single stakeholder's interest. In many ways it typifies what has been wrong with the policy intersection of quality and business.

[Section 5:3]

¹Leatherman, et al., "The Business Case for Quality: Case Studies and An Analysis," 22 *Health Affairs* 17 (Mar./Apr. 2003).

Given the increased importance of quality to the strategic mission of any health care enterprise,² a broader view for a business case for quality would ask “[i]s the intervention consistent with strategic goals, understandable, not too capital intensive relatively speaking, with positive impacts across stakeholders, and able to produce sustainable, acceptable margins, near term and long term?”³ True sustainability will only be achievable when the intervention maximizes positive impacts across stakeholders. Viewed from this perspective, the purely financial business case for specified quality interventions may vary somewhat among our subject triumvirate, but this more inclusive view of the ultimate goal can be seen to foster more collaboration rather than more conflict. It is this view which underlies the strategies set forth in this chapter.

§ 5:4 Interdependency: Who might help whom?

That a hospital has no business at all without the physicians who admit patients and order its services is well understood. The unique role of physicians in relationship to the hospital entity can be seen in the role of the organized medical staff which brings together for no reason but their use of the hospital facilities, otherwise disparate, usually independent (although some may be employed directly by the hospital), and sometimes competing physicians to surveil and assure the quality of care in the institution.¹ Virtually everything which happens in a hospital is in some measure derivative of a physician order. Even so, there are many improvements hospitals can make in their own systems and operations on issues where physicians are not task critical.

²Reinertsen, Finucane, and Wallace, “Straight Talk About Clinical Quality from Health Care CEO’s” (Ernst and Young Jan. 2004), http://www.uft-a.com/PDF/E_percent20and_percent20Y_percentPaper.pdf.

³Gosfield and Reinertsen, “Defining the Business Case for Quality,” http://www.uft-a.com/latest_issues/issues.htm#2bc9.

[Section 5:4]

¹Gosfield, “Quality And Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations,” AMA (Chicago 1998), http://www.ama-assn.org/ama1/pub/upload/mm21/quality_culture.pdf; Gosfield, “Whither Medical Staffs? Rethinking the Role of the Medical Staff in the New Quality Era,” *Health Law Handbook* (A. Gosfield, ed. 2003).

In many fundamental ways, though, hospitals cannot achieve success, whether in business or quality terms, without deep physician engagement.

The 100,000 Lives Campaign, for example, includes a plank which focuses on preventing surgical wound infections by requiring that physicians clip and not shave the hair at surgical sites. The hospital cannot make improvements there without physician cooperation. In the Medicare-Premier hospital pay for performance program, successes are demonstrated in the care for patients with acute myocardial infarction, coronary artery bypass grafts, heart failure, hip and knee replacement, and pneumonia; but these improvements occur where it is understood that “Leadership and culture are critical, clinicians need to be actively engaged in assuring best practices and focusing on process improvement is key.”² When hospitals seek to contain their costs within limited, case specific payments, like DRGs, they can only do so if physicians discharge patients timely and order cost-effective services, equipment and supplies which the hospital must then provide to their patients. That hospitals seeking to succeed in a performance-measured environment cannot do so without the willing collaboration of physicians seems ineluctably clear. It is surprising then that the tensions between hospitals and physicians have been so exacerbated, characterized by battles over economic credentialing, conflicts of interest and physician investments in competing enterprises.

Health plans, similarly, have no business model without the networks of providers that give them the ability to offer a managed care plan. Without a contracted network they are just an insurance product. Still further, many of the bases on which health plans are measured for quality really are occurring in physician offices. The vast majority of HEDIS measures reflect services rendered by physicians in their offices including preventive screening, immunizations, management of patients with osteoporosis, high blood pressure, diabetes care, cholesterol management, diagnostic testing, various drug therapies and more.³ The plans are measured on the extent to which their patients get these services, but

²Sr. Vice President of Premier, quoted in Loos, “Quality Connections,” *Modern Healthcare*, at 8 (May 9, 2005).

³<http://www.ncqa.org/Programs/HEDIS/>.

it is the physicians who provide them. Obviously the plan needs physician cooperation to succeed in this scoring exercise.

While this connection between the physicians who order and render care and hospitals and health plans may seem self-evident, the struggles between the relevant partners do not reflect this understanding. While not universal, a common perspective among physicians is that managed care plans do not pay enough, impose burdensome administrative requirements, and come between them and their patients far too often. At the hospital level, physicians increasingly resist demands that they render free on-call services to patients who may have little or no insurance and might sue them if things go wrong. They participate less and less in medical staff activities. Dissatisfied with hospital responsiveness to their demands for faster turnover in endoscopy suites and operating rooms, they are creating competitive ventures, (such as specialty hospitals, ambulatory surgery centers, MRIs, CTs and PET scanners, in-office physical therapy, endoscopy and more) which they control and from which they get a return on investment. If they seek businesslike financial opportunities with hospitals (*e.g.*, joint ventures, medical directorships) in their beleaguered struggle to succeed, they are spurned on the grounds that the fraud and abuse laws will not allow this. Yet the hospital expects them to devote time to doing the hospital's work in medical staff committees for which they have traditionally not been paid.

Can these marriages be saved?

II. THE LEGAL CONTEXT

§ 5:5 Generally

Three principal areas of the law have been erroneously wielded as impediments to more productive and creative collaborations for quality: (1) Stark; (2) the anti-kickback statute; and (3) the antitrust laws. A fourth new area of the law—Patient Safety Organizations—presents positive potential but many unknowns.

§ 5:6 Stark

The Stark statute has proven the most basic threat to economic relationships between hospitals and physicians. Since

the definition of “referral” is so broad¹ and because inpatient and outpatient hospital services are “designated health services,” any economic relationship between referring physicians and the hospital can trigger the statute’s prohibitions. These relationships include cash and in kind value, so hospital assistance to physicians with something other than compensation is also implicated. Moreover, Stark is a prohibition based statute—you either meet its requirements or the transaction is prohibited—in contrast with the anti-kickback statute safe harbors, which are less restrictive.

Employment and personal services agreements between hospitals and the physicians who refer to them are legitimate, although the payment amounts established by regulation for physician personal services have been restricted by the regulatory definition of “fair market value.” In the Phase II Stark regulations, the regulators defined fair market value for physician services with reference either to MGMA compensation scales or the average of four of six other compensation surveys, or by reference to what emergency physicians are paid in the community when there are at least three emergency departments in the community.² While the regulations do also address non-monetary compensation by a hospital to its physicians up to \$300³ as well as incidental medical staff benefits including Internet access, pagers, two-way radios, laundry, on-site meals, and parking,⁴ these make only minimal differences in physician’s lives.

As is explained more fully in the discussion below of new initiatives for collaboration, there are several regulatory exceptions which do offer far more significant opportunities for hospitals to help physicians with their own business case. These are the provisions pertaining to compliance training, recruitment and information technology support.

[Section 5:6]

¹“Any request for a service, item, or good payable by part B” including services or goods ordered as a result of a consultation (42 U.S.C.A. § 1395nn(h)(5)(A)).

²“Fair market value” definition, 42 C.F.R. § 411.351, 69 Fed. Reg. 1628 (Mar. 26, 2004).

³42 C.F.R. § 411.357(k).

⁴42 C.F.R. § 411.375(m).

§ 5:7 The Anti-Kickback statute

The anti-kickback statute is actually less of a problem than Stark because of the specific intent requirement as established in *Hanlester v. Shalala*.¹ Failure to conform to a safe harbor does not mean that a transaction violates the statute but that it will be evaluated in a facts and circumstances frame of reference based on prosecutorial discretion. As with Stark, fair market value is the gravamen of safety under this law and its safe harbor regulations. Unlike the Stark statute, though, the failure to meet a safe harbor does not mean the transaction will fail at the inception.

For the purposes of hospital-physician relationships, then, the transactions that are dealt with explicitly in the Stark exceptions essentially define the boundaries of possibilities, even though the anti-kickback statute is far broader in its scope. The safe harbors under the anti-kickback statute do allow for hospital-sponsored personal services and management contracts with physicians,² and bona-fide employment relationships.³ Because the anti-kickback statute is primarily focused on a far broader range of transactions and actors, the very few safe harbors under the anti-kickback statute do little beyond the Stark regulations to improve hospital-physician relationships oriented around quality. There are anti-kickback safe harbors which are relevant to managed care organization relationships with physicians such as those for risk sharing,⁴ discounts,⁵ and physician incentive plans,⁶ however they offer few creative opportunities in quality terms.

§ 5:8 Antitrust

The antitrust laws would not seem especially relevant to

[Section 5:7]

¹*Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995).

²42 C.F.R. § 1001.952(d).

³42 C.F.R. § 1001.952(i).

⁴64 Fed. Reg. 63504 (Nov. 19, 1999).

⁵42 C.F.R. § 1001.952(b).

⁶*See* 61 Fed. Reg. 13431 (Mar 27, 1996); 61 Fed. Reg. 69034 (Dec. 31, 1996); 63 Fed. Reg. 34968 (June 26, 1998) and 65 Fed. Reg. 40170 (June 29, 2000).

collaborations for quality, but particularly in connection with negotiation by providers for rates paid by managed care plans, the antitrust statutes are critical. While pay for performance and other measurement driven programs are usually instigated by plans, providers seeking a successful path through this thicket and those who choose a more proactive stance will have to confront these laws. In their safety zone statements of 1996, the Federal Trade Commission and the Department of Justice addressed both physician network joint ventures and multi-provider networks. Both offer significant opportunities for quality collaborations with potential specific impacts on the physician business case.

§ 5:9 Patient Safety Organization and Quality Improvement Act

In an effort to stimulate more substantial quality improvement believed to be impeded because of the risk of discovery of problems lurking behind any study of ways to prevent errors and improve care, Congress enacted the Patient Safety and Quality Improvement Act.¹ Providers who come together to engage in patient safety activities and report their “patient safety work product” to “patient safety organizations” (“PSOs”) can be assured that the data they are reporting will be protected from discovery and will be treated confidentially, at least as the law reads. Judicial interpretation may produce different results, since courts have undermined many state peer review protection acts.² But to be fair, most were enacted in the mid-1970’s and their drafting did not anticipate the very different context today in which plaintiffs seek access to such quality information.

“Patient safety activities” are broadly inclusive and go well beyond strict patient safety. Any organization seeking to be recognized as a patient safety organization must be involved in: efforts to improve patient safety and quality of health care delivery; collection and analysis of patient safety

[Section 5:9]

¹Pub. L. No. 109.41, 42 U.S.C.A. § 201.

²McCann, “Protection and Disclosure of Medical Peer Review Information,” *Health Law Handbook* (A. Gosfield, ed. 1989); Rodriguez, “Peer Review Protection Revisited: The Challenge of Transparency with Improvement,” *Health Law Handbook* (A. Gosfield, ed. 2003).

work product; development and dissemination of information to improve patient safety such as recommendations, protocols or information regarding best practices; utilization of patient safety work product for the purpose of encouraging a culture of safety and providing feedback and assistance to minimize patient risk; maintaining procedures to preserve work product; using qualified staff and engaging in other activities related to the operating of a patient safety evaluation system to provide feedback to the participants. A “patient safety evaluation system” means collection, management or analysis of information for reporting to or by a patient safety organization. The data protected includes written materials, reports, records, memoranda and analyses as well as oral statements. The statute provides for the creation of a network of patient safety databases. Patient safety organizations self-nominate and attest to their certification that they qualify.

The focus of this law is on the activities of “providers” which includes individuals or entities licensed or authorized to deliver health care services. These are virtually every kind of health care facility (*e.g.*, from hospitals to hospices, pharmacies to clinical laboratories and more) and includes practitioners’ offices even though they are not usually licensed or specifically authorized under state law. The practitioners whose activities are subject to the protections run the gamut from physicians to virtually every type of health care practitioner³ swept into the reference to “or other individual health care practitioner.”⁴ The secretary may further define in regulations other practitioners whose activities, studied and analyzed for statutory purposes, will be protected.

The statute is self-executing and effective upon enactment. Obviously some administrative mechanisms will be necessary for PSOs to list themselves. And the secretary’s regulations may clarify the import of many aspects of this statute. Nonetheless, this law has the potential to facilitate robust quality relevant activities. Hospitals and physicians may find it useful to participate jointly in these efforts. Because, however, data once reported to a PSO must be held in confidence for all purposes (subject to limited exceptions),

³Although dentists and podiatrists are not specifically named.

⁴42 U.S.C.A. § 299b-21(8)(ii).

there may be significant pitfalls in reporting to a PSO data that the contributor then wants to use commercially.

There are a host of outstanding questions about the practical implications of this law, but it may well support collaborative efforts between hospitals and physicians.⁵ To the extent they seek to undertake joint creation of patient safety work product to embrace their quality goals, that data will be protected from discovery, which could be particularly important given the heightened attention to patient safety failures and the connection of patient safety initiatives to the legal standard of care.⁶ Health plans may not serve as PSOs if they are a component of a health insurance issuer, and they do not fall within the definition of the “providers” whose activities under study are protected.

III. PHYSICIANS HELPING HOSPITALS

§ 5:10 Generally

In today’s quality-heightened competitive environment, the range of responsive hospital activities which cry out for physician involvement are multiplying. A high profile example is in the development and implementation of CPOE systems. One of the three leaps being pushed by the Leapfrog Group is the use of CPOE. The litany of derailed CPOE programs which failed because they neglected to include the perspectives of working physicians is impressive.¹ A CPOE program can only be as useful as the willingness of the physicians to enter orders into it. CPOE success stories entail a variety of techniques, including a strong clinician presence in the design, the development of adequate order sets to facilitate physician use, delving carefully into the bases for physician resistance and responding, making clear to the physicians the very demonstrable direct time savings and

⁵42 U.S.C.A. § 924(6)(1)(D).

⁶See Gosfield and Reinertsen, “The 100,000 Lives Campaign: Crystallizing Standards of Care for Hospitals,” *Health Affairs* 1560-70 (Nov./Dec. 2005).

[Section 5:10]

¹Gater, “CPOE Uncertainty,” 17 *For the Record* 25 (5-9-05), http://www.fortherecordmag.com/archives/fttr_050905p25.shtml; Patton, “The Right Dose of Technology Helps the Medicine Go Down” (11-01-05), http://www.cio.com/archive/110105/health_care.html.

integration with other systems which can then further save them time.² Unless the design and implementation meet physicians' needs, the programs will never fly. The new quality collaboration context goes well beyond CPOE, however.

§ 5:11 New quality initiatives

The new emphasis on quality is spawning decidedly different ways of conducting business for hospitals which would commit themselves to truly superlative, world class quality performance. The implementation of principles and processes from Toyota manufacturing processes, generally referred to as "lean manufacturing," is producing some spectacular quality successes throughout the country, defined both in terms of money saved for the facility and clinical results achieved for the patients. "Lean" organizations dedicated to systematically rooting out and eliminating those aspects of their operations and processes which do not contribute to explicitly articulated value in terms of the patient's needs are springing up from coast to coast. To make these new approaches work, often the involvement of physicians is necessary.

Virginia Mason Medical Center in Seattle was so convinced of the need for sweeping organizational change to become "lean" that they went so far as to send senior leadership to Japan to see how the Toyota production process worked.¹ Although that hospital employs its physicians, paying the expense of sending a referring independent physician to Japan would strike terror in the hearts of many compliance officers. Yet, this short-sighted, knee jerk anxiety about compliance is misplaced and essentially counterproductive to achieving quantitatively better performance. Garnering senior medical staff leadership support and full engagement on organizational culture change of this type would be essential. To make the rest of the hospital-proposed innovative processes work, to help to truly change the culture, there would have to be an understanding of how physicians would

²Baldwin, "Bringing Order to CPOE: 10 Make or Break Steps (and 5 myths)" *Health Leaders* (Nov. 2005), <http://www.healthleaders.com/magazine/cover.php?contentid=74158>.

[Section 5:11]

¹Institute for Healthcare Improvement, "Going Lean in Health Care" (2005), <http://www.ihl.org/NR/GoingLeaninHealthCareWhitePaper.pdf>.

be expected to and could meaningfully contribute. While physicians may not be essential in the design of process change, their ability to bring change to a grinding halt with their resistance is virtually unparalleled in hospital organizations.

Contrary to what many compliance officers and overly conservative attorneys might think, there are no fraud and abuse barriers to this type of an approach. Even if the physician sent on the trip happened to be a high admittance to the hospital who was also the elected President of the Medical Staff, this would not undermine the legitimacy of paying for her trip to Japan. Hardly a boondoggle, clearly a hospital team enterprise, with the results to be of benefit directly to the hospital itself and not the physician in her practice, this would be an extreme example of hospital compensation to a physician which could fit several exceptions under Stark (including for isolated transactions, fair market value and personal services) and anti-kickback personal services protections.

Reports of successes from IHI's Pursuing Perfection program make it clear that "Physicians must lead the work of improvement and align individual physician efforts. . . to improve. Administrative leadership must build the infrastructure to support physicians in this effort."² In lowering length of stay, although data provided to physicians was a critical element of success, part of the ability to achieve dramatic improvements in cost effective care is "involving physicians from the beginning."³

To really propel hospital quality to exponentially better levels, entirely new ways of thinking about and managing hospital processes are emerging. A new focus on "flow" is such an example. Moving patients more expeditiously through the facility and among departments results in better outcomes for patients, higher revenues to the hospital and more staff and patient satisfaction. Examples of "flow" improvement projects include: (1) freeing up bed space in intensive care units which in turn prevents hospital emergency departments from diverting patients, (2) creating more efficient operating room use through scheduling of elective

²Colones, "Team Effort," *Modern Healthcare*, at 25 (Feb. 7, 2005).

³Ferguson, "When Quality Means Business," *Modern Healthcare*, at 27 (Feb. 21, 2005).

surgeries, (3) better and more efficient utilization of cardiac catheterization laboratories, (4) shortening times of getting patients from the emergency department to the floors, (5) shortening times in getting patients from one department to another, and so on.⁴ The range of flow related issues in hospitals is diverse. Many improvements are managed through redesign of organizational processes and different deployment of hospital personnel. But a good number of the flow success stories turn on the use of standardized protocols, rather than relying on individual physician orders. To some physicians this can represent a disenfranchisement of their professional prerogatives, and, typically, they reap no personal economic benefit from these efforts.

Additional efforts at “Transforming Care at the Bedside”⁵ are addressing other fundamental health quality issues, many of which are aimed at optimal deployment of nurses and other clinical personnel. But even improvements such as a shift to using discharge day appointments entails physician cooperation. This mechanism plans in advance the marshalling of the range of services necessary to effect an appropriately supported, well orchestrated patient discharge, reducing delays and improving patient satisfaction; but it also requires physician cooperation with the scheduled visits that are necessary to complete the discharge.

In the 100,000 Lives Campaign, a number of the planks will succeed based, in part, on physician support and involvement. Perhaps the most physician intensive of the planks is the prevention of surgical site infection by using a bundle of evidence based services including appropriate hair removal, guideline-based timing and use of perioperative antibiotics and tight perioperative glucose control. A hospital can adopt protocols regarding these actions, along with standing order sets that trump individual physician orders, but a physician who continues to shave his patients can derail the enterprise. Similarly the use of “ventilator

⁴For success stories of improvement of flow, and the techniques to accomplish it, see IHI’s Improvement Reports, where hospitals which have undertaken these projects report the steps they took to accomplish significantly improved results. <http://www.ihl.org/IHI/Topics/Flow/PatientFlow/ImprovementStories/MemberReportImprovingFlowofPatients.htm>.

⁵<http://www.ihl.org/NR/rdonlyres/2351AD3E-FFCE-45EC-8A4C-E0E186DCD8B9/0/TCABWhitePaper2004.pdf> (2004).

bundles” to lower mortality in patients on ventilators which includes elevating the head of the bed by 30 degrees, daily sedation vacations, glucose and peptic ulcer controls, and daily readiness to wean assessments, can only succeed if physicians do not write superseding or conflicting orders. Therefore, to make these types of quality driven interventions work, the willing and enthusiastic support of the medical staff is critical.⁶ How is this likely to be accomplished?

The real challenge for hospitals in obtaining the involvement and commitment of physicians whom they need to make these types of substantial advances is to make the real and compelling case to the physicians that their involvement in this activity will also redound to their own benefit. An example of how this can work is found in the story of the Hackensack University Medical Center which had employed the usual techniques to motivate physicians to employ evidence-based medicine in the treatment of pneumonia. They disseminated the guidelines; they lectured on them at grand rounds; they talked about the need to do this. Nothing worked. Eventually, medical staff leaders settled on a process by which advance practice nurses would closely scrutinize the delivery of pneumonia care and more to the point, actually intervene when care fell below the standards. This nurse empowerment has had powerful effects in several other hospital initiatives as well.⁷ The key is that in the long run the physicians came to see the nurse involvement as saving them time from having to interrupt their own days to intervene at the hospital during patient office hours or otherwise. To connect with these aspects of physician needs is only part of what is necessary to enlist genuine physician engagement.

§ 5:12 Principles of engagement

In addition to understanding where physician engagement

⁶Although IHI stories are at the leading edge of new approaches to quality improvement, hospitals that have ranked well on the Solucient Top Heart Hospitals cite, among other factors, collegial rapport between cardiologists and cardiothoracic surgeons and skill of physicians as critical to achieving good results. These are in addition to new technology and aftercare by nurses. Greene, “Taking Quality to Heart,” *Modern Healthcare*, at 24-27 (Oct. 31, 2005).

⁷Morrissey, “Following nurses’ orders,” *Modern Healthcare*, at 36-42 (Aug. 26, 2002).

in quality initiatives will be essential, the use of some principles of engagement can maximize potential physician contribution.¹ To garner physician credibility for a physician-critical hospital program, the first rule is to involve the physicians at absolutely the earliest stages of conceptualization, design and implementation. Physicians will suspect initiatives brought to them by hospital administration if they perceive their only role will be to bless activities already decided upon. Although not all physicians can be involved in all projects, nor should they, whatever physician involvement there is should not only be transparent, but publicized throughout the medical staff, so there is no question that physician representation has been present throughout.

The physicians engaged in the program need not be selected by the medical staff, but must be perceived by other physicians as the leaders of the medical staff clinical culture. While often these are elected leaders in medical staff governance, just as often the true leaders—and especially those who will actually do the substantive work—may not hold a title. These are physicians who enjoy peer respect for their clinical care, demonstrate integrity and selflessness in acting as physician representatives, are good communicators who share information with other physicians and seek their input, are open to learning new information about what the hospital is doing and can share that learning with their colleagues.

The processes by which programs are brought to fruition should explicitly acknowledge that often there has developed a lack of trust between the medical staff and the hospital; and that trust is earned, not commanded. To earn physician trust, the hospital representatives must do what they say and say what they do, consistently over time. Believable con-

[Section 5:12]

¹These principles were first enunciated in 1998 in Gosfield, “Quality And Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations,” AMA (Chicago 1998), http://www.ama-assn.org/ama1/pub/upload/mm21/quality_culture.pdf, and then were expanded upon in 2003 in Gosfield, “Whither Medical Staffs? Rethinking the Role of the Medical Staff in the New Quality Era,” *Health Law Handbook* (A. Gosfield, ed. 2003). Their utility is now patently evident in the multiple comments here regarding the factors contributing to success in the new quality initiatives.

sistency also requires open, frequent and candid communication including the sharing of raw data underlying the hospital's analysis of the problem, including highly sensitive strategic information. Sometimes such information can be damaging if revealed publicly. Therefore, all the parties involved must recognize the confidential nature of the undertaking; and these principles must be both articulated and adhered to in every respect. The hospital must demonstrate a willingness to respond to potential physician challenges to any data disclosed, in a spirit of intellectual inquiry. Physicians are trained to question and probe scientific data and they will take the same path in forging hospital-physician collaboration programs.

It is the implementation of these principles that can best draw physicians into settings where they will not be paid for their work; because most true physician leaders have a deep commitment to their patients' care and the safety and quality of the environment to which they bring them. The extent to which physicians perceive themselves as their patients' advocate, intermediary, fiduciary and even personal representative is absolutely extraordinary and a critical reason physicians do any of this work for free. Hospitals must acknowledge and even articulate this acknowledgement if they are to win physician favor for these fundamental quality undertakings. For this reason, documentation of the principles of engagement for all involved to see and how to is also a useful technique to enhance physician support and involvement.²

§ 5:13 Medical staff work

It must be acknowledged, though, that hospitals, even forward looking institutions, have had increasing difficulty engaging physicians in the hospital's work. In 2003, identify-

²This is not to say that physicians do not present their own set of challenges in the way they interact with hospitals, but this consideration is about how hospitals can best obtain physician involvement in hospital quality initiatives. See Gosfield, "Quality And Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations," AMA (Chicago 1998), http://www.ama-assn.org/ama1/pub/upload/mm21/quality_culture.pdf; Gosfield, "Whither Medical Staffs? Rethinking the Role of the Medical Staff in the New Quality Era," *Health Law Handbook*, § 4:7, n.2 (A. Gosfield, ed. 2003), for other issues pertaining to physician values and behaviors.

ing demands which steal from physicians' the time and touch¹ they need in their relationships with patients, a group of national, high level chief medical officers and group leaders cited the hospital's demands for their time to do the hospital's business as distracting and counterproductive to time and touch.²

Today, hospitals are increasingly confronted with the problem of not being able to muster responses from the medical staff to participate in activities traditionally part of the volunteer tradition of medicine. With the loss of free clinics as part of hospital charitable missions, and the advent of Medicaid to pay for formerly charitable cases, along with the policy and business demands that physicians be more businesslike in their business behaviors, physicians have found the work of the organized medical staff increasingly irrelevant to them. Against this background today, as physicians struggle with crushing administrative burdens, soaring malpractice insurance expenses and lowered reimbursements, hospitals still expect them to contribute their time to the hospital's enterprise without compensation. This is absurd. Time is money and this is certainly the case for physicians. Paying physicians fair market value as defined by Stark for the time they spend in all of these initiatives is entirely appropriate and legitimate.

Since only 20 percent of most medical staffs members account for 80 percent of the work in the hospital, the functional, organized medical staff is actually a small subset of the physicians who self-identify as hospital staff members. Successful hospital strategies to garner the involvement of the 20 percent will, per force, recognize the differing needs of this group as distinct from the less involved 80 percent. But there is no question that to meet the hospital's needs associated with quality as mandated in law, accreditation and competitive forces, hospitals are going to have to look increasingly to paying for this consultation.

Traditionally, the work of the medical staff has been

[Section 5:13]

¹Gosfield, "The Doctor-Patient Relationship as the Business Case for Quality," 37 *J. Health Law*, pp. 197, 203 (Spring 2004).

²See Gosfield and Reinertsen, "Doing Well by Doing Good: Improving the Business Case for Quality" (June 2003), <http://www.uft-a.com>.

autonomized by physician choice into a separate activity supported by medical staff dues. These dues are seen as preserving the independence of the medical staff, which, of course, is not independent at all, and gets its entire *raison-d'être* from the hospital's quality mission. Most medical staffs maintain their medical staff dues bank account under the hospital's tax exempt aegis (and lose those funds to hospital bankruptcies when they occur). They spend the money on the annual staff "prom" and on paying for the medical staff counsel to advise them and write their bylaws. Occasionally they pay stipends to the President of the Medical Staff because of the time he will have to devote to the medical staff and divert from his own practice. The ultimate effect of this approach has been to create suspicion as to the political bona fides of physicians who would accept payment from the hospital for their service in support of its mission. In light of the end of the era when participation in the medical staff leadership was an honorific that bestowed prestige and potentially economic benefit, physicians who perform these functions lose money from their practices and many are disinclined to do that.

Hospitals increasingly will have to consider paying the independent members of the medical staff who make quality happen in the hospital and do so through these new types of quality activities involving flow, CPOE, the six planks, transformed care at the bedside and more. And, in the design and piloting of these programs, they likely will have to pay as they would any consultant—on an hourly basis consistent with the Stark standards on fair market value for physician services. Does this mean everything that physicians do at their hospital must now be revenue producing for them? Of course not. Most of the marvelous accomplishments documented by the IHI involve either physicians employed by the hospital or its system, or independent members of the medical staff who contributed their time because they believe in the purpose of the hospital's mission and want their patients to be in a safe and high quality setting, where they will be practicing. But, where hospitals really need the involvement of private practicing physicians to assist them in these types of quantum leaps in care, they cannot expect that all of these services will be rendered for free, nor should they be fearful of paying for the economic value of what they obtain.

§ 5:14 Gainsharing

One way that hospitals have tried for years to bond with physicians, has been through “gainsharing” programs, seeking to share with the physicians the economic benefits of their contribution to savings. Stymied by the several fraud and abuse laws that do not allow a hospital to pay a physician to reduce services to patients,¹ gainsharing has had a checkered history.

When the DRG program was introduced in 1983, it did not take long for some hospitals to figure out that if they gave physicians some of the money saved by shorter lengths of stay and more efficient care, their results might be better. Even then, though, the government came down hard on the Paracelsus company and its gainsharing program. Stemming from a complaint from the American Medical Association that the gainsharing program was paying for referrals,² the government rejected the approach and concept, as violative of the law. This eventually led to a far broader investigation of Paracelsus which resulted in a \$4.5 million settlement alleging false cost reports.³ Little further was heard regarding this type of bonding technique for many years. A new generation of consultants discovered the financial incentives of DRGs anew in the late 1990’s and reinvigorated the initiative. It was soundly thrashed by the OIG in a special advisory bulletin in 1999.⁴ One cardiac program was approved⁵ some months later, but nothing more happened for another almost six years.

In 2005, a new approach to gainsharing emerged. Oriented around procedural services, such as surgeries and cardiac

[Section 5:14]

¹See King and Lothian, “Gainsharing—Life Before and After the Bulletin,” *Health Law Handbook* (A. Gosfield, ed. 2000) and Gosfield, “Making Quality Happen: In Search of Legal Weightlessness,” *Health Law Handbook* (A. Gosfield, ed. 2002).

²Wallace, “HHS allows a year to lapse with no ruling on incentive package legality,” *Modern Healthcare*, at 103 (Oct. 10, 1986).

³*USA v. Paracelsus Settlement*, No. 86-106 (D.C. CA Nov. 28, 1986).

⁴OIG, “Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Sources to Beneficiaries” (July 1999), <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

⁵OIG Advisory Op. No. 01-1 (Jan. 11, 2001).

catheterizations, a single consultant obtained six favorable advisory opinions where the core of the proposed programs was not reducing length of stay or lowering overall cost, but rather on standardizing supplies in the operating rooms and cath labs.⁶ For the hospital this would lower expenses by lowering the numbers of varying types of supplies (*e.g.*, instruments, stents, catheters) the hospital would have to keep in stock.

The money to be paid to the physicians who help the hospital decide how and what supplies to focus on is limited. The payment is a one-time payment of 50 percent of only the first year cost savings. Some have criticized these approaches as creating patient suspicion that physicians will skimp on care to get more money.⁷ By definition gainsharing is not a sustainable model as a business strategy and can only work once. Although, standardization is a hallmark of patient safety, that is not the primary thrust of these programs, which are cost savings initiatives at their core. At best, gainsharing should be seen as a very limited opportunity to get physicians to help hospitals. Still it may be used to gain some physician involvement.

§ 5:15 On-call coverage

The obligations of EMTALA¹ fall predominately on the hospital to evaluate, stabilize and only then transfer patients who present to the emergency department. Although there is a \$50,000 civil money penalty available to the government to impose on physicians who fail to respond to a request to attend a patient when that physician is on-call, physicians are routinely opting out of those categories of privileges that require that they take call.² With visit volume increasing and a quarter of these visits requiring specialist care, the

⁶OIG Advisory Op. No. 05-01 (Feb. 3, 2005); OIG Advisory Op. Nos. 05-03 and 05-04 (Feb. 17, 2005); OIG Advisory Op. Nos. 05-05, 05-06 and 05-07 (Feb. 25, 2005).

⁷Abelson, "Dr. Saves-a-Lot," *N.Y. Times*, at C1 (Nov. 18, 2005).

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¹42 U.S.C.A. § 1395dd.

²See "On Call Physicians at California Emergency Department: Problems and Potential Solutions" (Jan. 2005), California Health Care Foundation, <http://www.chef.org/topics/hospitals/index.cfm?itemID=10558>.

problem is a big one. The quality issues here include delayed treatment or diagnosis because of unavailability of enough physicians in the requisite specialties.

Hospitals still mandate on-call coverage as a condition for privileges. In California, a recent study found 78 percent of hospitals still require on-call coverage but only 17 percent of them say it is working well.³ But reimbursement rates are so low, and so many patients may have no insurance coverage at all, the days when covering call in the emergency department could build or sustain a practice by finding unaffiliated patients are long over. Increasingly, for some specialties, multiple hospitals in a single market share a dwindling pool of on-call physicians.

More hospitals are using hospitalists—physicians whose entire practice is focused in the hospital with no other private practice responsibilities—but in high end specialties like infectious disease, this approach does not work. Sixty three percent of California hospitals pay physicians a stipend for on-call coverage (ranging from \$21 a month for primary care to \$1,850 a month for plastic surgery). Thirty nine percent pay a per case amount up to a guaranteed level. Until other solutions are adopted (*e.g.*, legislative change, better managed care payment, removal of legal hurdles for hospitals to share on-call coverage panels⁴) the use of creative stipends is likely to meet short-term demand. An example is tiering payment by “beeper intensity”—how often the doctor is likely to be called, by specialty, with highly intense need paid more. These payments at fair market value for their availability do not violate Stark or the anti-kickback statute, even though the physician may get to bill for some services he renders while on-call.

§ 5:16 Avoiding trouble

Hospitals have been known to award compensation to high volume physician referral sources just to curry favor with

³“On Call Physicians at California Emergency Department: Problems and Potential Solutions,” at 5 (Jan. 2005), California Health Care Foundation, <http://www.chef.org/topics/hospitals/index.cfm?itemID=10558>.

⁴EMTALA is unclear as to whether this is permitted and some believe the antitrust laws are also a concern.

them. In the notorious *LaHue* case,¹ over a period of a dozen or more years, the hospital system revised their medical director agreements with the physician brothers LaHue who brought many of their nursing home patients to the facility. Their compensation was purportedly for their management of a special program for nursing home patients admitted to the hospital—most of whom were the patients of these physicians. Apparently the defendants were unsuccessful in demonstrating that this relationship had some reason to exist apart from the physicians' referrals. The fact that what they did for the hospital, if anything, was fundamentally restricted to activities involving their own patients whom they were treating in the institution and for which they were billing Part B anyway for their physician services, further undermined the legitimacy of the transaction. The fact that the case was brought criminally, and that two lawyers advising the hospital were indicted as well, cast a post-decision chilling effect of unprecedented proportions on medical directorships and other forms of hospital-physician compensation relationships involving private practice physicians who refer to the hospital and admit many patients there.

Most of this reaction is excessive. The real test of whether such compensation is legitimate is whether it would be expected that a hospital would need the special expertise that physicians can bring to bear in what they do to perform the contracted-for function, even if that physician had zero patients to send. Moreover, the Stark regulations now establish in the definition of "fair market value," the appropriate rate to pay.² This ought to remove much of the anxiety about paying referring physicians to do work for the hospital—including, particularly, developing quality driven processes—where those processes do not directly benefit them economically. Indirect effects, though, can also solidify physician involvement in these initiatives, along with other explicit strategies by which hospitals can further the development of the physicians business case for quality while helping themselves.

[Section 5:16]

¹U.S. v. LaHue, 998 F. Supp. 1182 (D. Kan. 1998), aff'd, 170 F.3d 1026 (10th Cir. 1999).

²See "Fair market value" definition, 42 C.F.R. § 411.351, 69 Fed. Reg. 1628 (Mar. 26, 2004).

IV. HOSPITALS HELPING PHYSICIANS

§ 5:17 Generally

That hospitals cannot survive without physician involvement in their quality mission is now clear. What has been less clear is the significant role that hospitals can play in helping physicians help themselves. Not only can this lead to the long sought after bonding of the independent physicians with the sponsoring hospital as their significant other, even in communities with a significant number of “loyalty splitters”—physicians who are truly active on more than one staff—these efforts can directly redound to the hospital’s benefit, without winning the exclusive fidelity of these physicians. A classic example is standing order sets.

§ 5:18 Standing order sets

The value of standing order sets is usually stated in the hospital’s terms. To standardize care in accordance with the evidence by virtue of unitary standing orders is part of the change by hospitals to more evidence-based medicine. Many hospitals have traditionally allowed physicians to maintain personal and idiosyncratic standing order sets. In the world of standardization this is an obsolete and counterproductive approach.

About ten years ago, at Park Nicollet in Minneapolis, the decision was made to improve performance in the treatment of acute myocardial infarction. A critical change was the establishment of standing order sets which meant that physicians did not have to write specific, personal orders to begin treatment of the heart attack patient presenting in the coronary care unit (“CCU”). Worked out between the Department of Cardiology physicians and the nursing staff in the CCU, the system gave physicians the ability to customize the standing orders for their patients as necessary without having to write the Russian novels otherwise required to implement the appropriate treatment regimen. Over time their quality results skyrocketed, and the physicians saved

significant time out of their day.¹ After ten years of experience, their experience was so positive that it won national awards and has been expanded throughout the hospital.² This time savings has also been noted in Texas.³

Virtually any standardization—in clinical processes, in documentation, in use of non-physician practitioners—will save time which benefits physicians directly. None of this implicates any of the legal concerns often raised in hospital-physician collaborations. The loss of time to administrative tasks is one of the most difficult challenges physicians confront on a daily basis. It represents a real quality problem for them, and their patients,⁴ and it drains their energies and satisfaction. Hospitals which facilitate regained time for physicians will draw physicians to them; and those institutions which use this as a measure of the value of an intervention on which they seek physician involvement will improve their own quality results at the same time.

§ 5:19 Clinical integration

In addition to time, physicians are also very concerned about money and particularly their reimbursement rates. Medicare has continued to lower reimbursement under the Medicare Fee Schedule and some managed care plans in major markets are paying significantly less than that. This erosion in physician revenues has contributed both to their competitive business behaviors which hospitals decry as well as to their resistance to working with the hospital, since time spent there is income lost in the office or other clinical care. Clinical integration offers a major opportunity for

[Section 5:18]

¹Reinertsen, “It’s About Time,” 2 *Dis. Mgt. and Quality Improvement Report*, pp. 1-7 (April 2002), <http://www.uft-a.com/PDF/leadarticle.pdf>.

²Erikson and Platt, “The Quality Continuum: Award Winning Care Delivery Innovations,” *Group Practice Journal* (April 2002), pp. 1-8.

³Texas Medical Foundation, “Implementing Standing Orders for AMI,” http://66.102.7.104/search?q=cache:X50DlxL_XiEJ;http://www.tmf.org/hospitalqi/ami/SuccessStorieswebex021704.ppt+hospital+standing+order+sets&hi=en&start=1&ie=UTF-8.

⁴See Gosfield, “The Doctor-Patient Relationship as the Business Case for Quality,” 37 *J. Health Law*, pp. 197-223, at 203 (Spring 2004), and Gosfield and Reinertsen, “Doing Well by Doing Good: Improving the Business Case for Quality” (June 2003), <http://www.uft-a.com>.

hospitals to help physicians advance their circumstances on this score, while improving quality.

In the 1996 “Statements of Antitrust Enforcement Policy in Health Care”¹ the Federal Trade Commission and Department of Justice reiterated and clarified safety zones they had published some years earlier, including those pertaining to financial integration and messenger model networks. But they went much farther than that in offering an opportunity that is not strictly a safety zone, but rather is stated in hypothetical terms of scenarios against which there would be no enforcement. This is clinical integration. For the purposes of our discussions here regarding advancing the hospital’s quality mission by helping the physicians, there are two versions of this opportunity which are relevant.

In much the same way that hospitals have good reason to standardize to the science as much as possible to both improve quality of care and enhance their efficiency in economic terms, physicians also have good reason to engage in such behaviors.² To standardize within physician practices in accordance with clinical practice guidelines and evidence-based medicine could improve physician financial margins by rooting out wasted time and resources while improving quality performance. Standardization, not only of clinical processes, but of much more, including but not limited to documentation of care delivered, how examinations rooms are equipped, and what tasks are best performed by non-physician clinicians, certainly would enhance the physicians’ business case. But standardization also provides the foundation for clinical integration.

The enforcers have said that if otherwise competing physicians—a group of unaffiliated cardiologists, oncologists or orthopedists for example—were to come together and engage in five basic activities, they may bargain collectively over rates, even fee for service rates, with managed care plans. To take advantage of this opportunity, the physicians have

[Section 5:19]

¹Statements #8 and #9, “Statements of Antitrust Enforcement Policy in Healthcare (Aug. 28, 1996), Department of Justice and Federal Trade Commission, <http://www.ftc.gov/hlth3s.htm>.

²See Gosfield and Reinertsen, “Doing Well by Doing Good: Improving the Business Case for Quality” (June 2003), <http://www.uft-a.com>.

to: (1) use standardized protocols, clinical practice guidelines (“CPGs”) or care pathways to drive how they deliver care; (2) internally monitor the participating physicians and profile the extent to which they conform with those CPGs; (3) invest in infrastructure with time and money to make these activities happen; (4) take corrective action against physicians in the network who are not measuring up; and (5) share the resulting data with payors. These five components are not the only way clinical integration can occur, but they are the factors the FTC identified in 1996. Where these activities are occurring, for real, then the fee bargain is ancillary to the reason to come together and the enforcers would not move against the network.³

There are a host of ways in which hospitals can facilitate these activities: from helping to identify CPGs to use, to facilitating access to infrastructure the hospital may have for monitoring (*see* § 5:21), to conducting the profiling involved, to helping construct the rates to be paid. Because of the Stark exception for compliance training (*see* § 5:20), these types of assistance are also protected from fraud and abuse liability.

In addition to physician-only clinical integration, the multi-provider network opportunities anticipate hospitals and physicians coming together. Here, in addition to the same five bedrock activities, the regulators also add recognition of a formal PHO mechanism for this purpose, where the physicians and hospital are in a single corporate structure, and the physicians are paid fee for service. Still further, where a PHO bargains to provide services paid on a per case basis, the protection will also apply where the other elements of standardized care, evaluation and monitoring, infrastructure to perform, corrective action and sharing of data are present. Under this mechanism the PHO would be paid a single case rate to cover hospital and physician care for specified categories of care. The enforcers cite bone marrow transplants, but in their recognition that their hypothetical PHO would be looking to develop new payment mechanisms, they were also tacitly acknowledging their own

³For an excellent elucidation of clinical integration generally, *see* Leibenluft and Weir, “Clinical Integration: Assessing the Antitrust Issues,” *Health Law Handbook* (A. Gosfield, ed. 2004); <http://www.gosfield.com/PDF/ch1PDF.pdf>.

limitations in terms of stating the range of protected behaviors. The enforcers expect innovations to arise that they will have to address. For example, their hypothetical example contemplates a formally structured PHO as a separate corporation, yet there is nothing to require this approach; and hospitals and physicians could come together functionally while remaining legally separate. Case rates could be established for physicians apart from the hospital which would be paid separately. They could determine on the front end who gets how much of the bargained for payment. Along these lines, there are new payment models developing out of the transitional moment of Pay for Performance⁴ to go much farther along this pathway. See discussion of PROMETHEUS payment at § 5:28.

These clinical integration opportunities were first made available almost ten years ago. They have, surprisingly, been very little used. They have been called into play mostly in defensive postures—the providers who are being enforced against argue that they are clinically integrated and therefore their collusive fee bargain should be protected; or the enforcers have said in many settlements to date, “you could have done this if you had been clinically integrated.”⁵ There is only one instance so far of an FTC Advisory Opinion approving in advance a proposal regarding clinical integration⁶ and another instance where the FTC enforced against a physician network and ordered them not to proceed with PPO bargaining until the FTC approved them as sufficiently clinically integrated, which approval has now been granted.⁷

The techniques used by both networks are not the same, which points to the fact that the FTC is open to a range of activities which will improve quality and efficiency, even where collective bargaining is involved. Today, the forces

⁴See Gosfield, “P4P: Transitional At Best,” *Managed Care* (Jan. 2005), http://www.managedcaremag/archives/0501/0501.p4p_gosfield.html.

⁵See Gosfield, “Our Take on FTC Actions,” at <http://www.gosfield.com/newissues.htm#ftc> and Gosfield, “Enough Clinical Integration,” at <http://www.gosfield.com/newissues.htm#eci>.

⁶In re Med South (FTC Advisory Opinion 2002), <http://www.ftc.gov/bc/adops/medsouth.htm>.

⁷In re Brown and Toland (FTC Staff Review 2005), <http://www.ftc.gov/os/adjpro/d9306/050405cpbresponsetbnotice.pdf>.

driving toward standardization to evidence-based medicine and CPGs, transparency and reporting of data, profiling and measurement are far stronger than they were in 1996. Physicians who do not want to merge their practices still want to perform better—both clinically and financially. Clinical integration is their answer. Hospitals should look to the issue of how to help physicians improve their performance and enhance their financial margins through these techniques. Even if no one pays them differently, vastly increased standardization will advance their business case; and the hospital can help them. Looking to the Stark protections on these points is particularly helpful.

§ 5:20 Compliance training

The Stark statute’s limitations on financial relationships between hospitals and physicians are breathtakingly broad and badly drafted to boot. Faced with the profound practical dilemmas posed by the statute, the regulators mitigated by regulations the blunt force effect of the statutory preclusions, and also staked out new turf in the arenas of exceptions. This is how the exceptions for incidental medical staff benefits,¹ fair market value payments to physicians,² charitable donations by physicians,³ academic medical center interrelationships⁴ and professional courtesy⁵ got created.

For our discussion, one of the most significant exceptions is for hospital-supplied compliance training.⁶ It permits an entity, not necessarily only a hospital, to provide “compliance training” to a physician (or immediate family member) who practices in the entity’s local community or service area, when the training is held locally. The scope of what qualifies as “compliance training” is where the real quality related opportunities arise.

As Medicare has aligned itself more and more with private

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¹42 C.F.R. § 411.357(m).

²42 C.F.R. § 411.357(l).

³42 C.F.R. § 411.357(j).

⁴42 C.F.R. § 411.356(e).

⁵42 C.F.R. § 411.357(s).

⁶42 C.F.R. § 411.357(s).

insurance in terms of pay for performance, performance measurement, efficiency measures, demonstration projects on quality⁷ and has expanded its fraud and abuse penalties to quality concerns,⁸ compliance now goes far beyond understanding CPT and ICD-9 coding on physician claim forms, to entail the very issues physicians must address in their own practices to fulfill their own business case. Still further, as hospitals engage physicians in their own quality initiatives, because these initiatives relate to regulatory requirements, it draws them under the rubric of compliance training.

The point is that hospitals can affirmatively provide, pay for, and implement training programs for physicians to advance their own business case, so long as they do not receive CME credit for the training as well. From evidence-based medicine, to techniques of standardization, adherence to CPGs, documentation, physician office flow, use of non-physician practitioners and almost anything that relates to the new world of performance measurement and quality reporting—all could fall into “compliance training”⁹ since all are increasingly part of the federal, state and local regulatory context with which physicians must contend. Clinical integration for performance and efficiency also falls into this arena since it is an announced federal regulatory issue. Other aspects of physician quality initiatives with which hospitals can help are technology infrastructure.

§ 5:21 Information technology support

The need for more sophisticated technology to propel quality even further has recently been recognized in many ways including the designation of a health care information technology czar within the Department of Health and Hu-

⁷See Gosfield, “The Performance Measures Ball: Too Many Tunes, Too Many Dancers?,” *Health Law Handbook* (A. Gosfield, ed. 2005).

⁸See Gosfield, “Making Quality Happen: In Search of Legal Weightlessness,” *Health Law Handbook* (A. Gosfield, ed. 2002).

⁹Although each such training program would have to be evaluated to determine whether it qualified.

man Services.¹ For all the calls for more technology use, though, the fraud and abuse laws and particularly Stark, have been significant barriers to hospitals facilitating physician implementation of technologies that would enhance the interaction between and among them as well, to permit physicians to function more efficiently themselves.

This major obstacle was diminished in some measure with the enactment of the Medicare Prescription Drug Benefit in § 101 of the Medicare Modernization Act² wherein the Secretary of HHS was directed to adopt standards for electronic prescribing that would create an exception under Stark and the anti-kickback statute to allow hospitals to help physicians with this new approach. The most basic notion has been that hospitals would be permitted to flat out donate the relevant technology to their staff members. With prescription drugs as the launch platform, CMS has published proposed regulations that go further in terms of permitting hospitals to help physicians with electronic health records as well.³ The new proposed Stark exceptions are intended to be consistent with anti-kickback safe harbors too,⁴ but since Stark is a prohibition-based statute, its regulatory exceptions have to be navigated before the anti-kickback issues can even be considered, where physicians are concerned.⁵

The fundamental e-prescribing exception would permit the hospital to donate the equipment and training “necessary,” as the statute requires, for electronic prescribing. Donations may be made to members of the medical staff, but only those who routinely furnish services at the hospital. This limitation would preclude assistance to primary care physicians who refer their patients to the institution but do not

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¹Ca. Health Care Foundation, “HHS Names Health IT Chief, Announces Standards Adoption,” *iHealthBeat* (May 7, 2004), <http://www.ihealthbeat.org/index.cfm?Action=dspltmoitemID=102590>.

²Pub. L. No. 108-173.

³70 Fed. Reg. 59182 (Oct. 11, 2005). The comment period on the proposed regulations closed on Dec. 12, 2005, so any final regulations will not be issued for at least six months after that, if then.

⁴See 70 Fed. Reg. 59015 (Oct. 11, 2005).

⁵The anti-kickback statute would also apply to pharmacists and other non-physician prescribers, but Stark is only relevant to physicians, and this chapter only addresses the physician-centric issues.

routinely round there. The donations may not be used to replace similar technologies physicians already own out of a concern that physicians will divest themselves of their own technologies in favor of donated technologies.

The broader electronic health records provision allows the donation of software, hardware and training, but the programs at issue must include an electronic prescribing component and that must be a substantial use of the donated goods. Still further, physicians must be able to use the protected technology for all patients without regard to payor status, even though these regulations only have relevance to the Medicare prescription drug benefit. Here, though, there is almost more yet to be determined than there is stated in the proposed rule. One problem is that the secretary is expected to publish standards for certified EHRs and particularly for those which are interoperable. Therefore the proposed rules distinguish between pre-interoperable donations and post-interoperable donations.

The range of questions on which the regulators have called for comments speak to their very nascent understandings associated with these new technologies. For example, commenters are asked to address matters ranging from what kind of dollar cap should be placed on what can be donated including how much it costs physicians to purchase these types of technologies, how to avoid abuse in the case of physician divestiture of existing technologies, how to quantify in a multi-functional software package how substantial the electronic prescribing component is, how to avoid hospitals using this exception to recruit physicians to their staffs, particularly when those physicians are primarily dedicated to a competing institution, and whether the electronic prescribing exception should be extended to prescribing for other services that are not drugs such as supplies and laboratory tests.

No matter the specific resolutions of those issues, the most critical point is that in a very short period of time, hospitals will be in a position to provide this type of assistance and support to the members of their medical staffs without fear of legal reprisal, both relieving the physicians of significant financial expenditures as well as facilitating their advancement on the quality-efficiency pathway. This is a very major development even with the contemplated restrictions.

§ 5:22 Staffing services

For those physicians on the medical staff who are actively engaged with the hospital on a daily basis, making rounds and participating in committees, the issues already discussed with respect to further engagement will be meaningful. For the other 80 percent of the physicians on the medical staff, and particularly the primary care physicians who may no longer even come to the hospital, how the hospital can help their business case becomes more of a challenge. One overlooked area which can advance the business case for quality would be where the hospital establishes a non-physician practitioner staffing function.

There are many physicians who toy with the idea of hiring nurse practitioners or physician's assistants or clinical nurse specialists (here referred to together as "non-physician practitioners" or "NPPs") to help them in their offices. But these highly trained personnel are not inexpensive. Many of these physicians do not believe they have sufficient work to justify the expense and, faced with shrinking revenues, are terrified to take the risk. These physicians are prime targets for the hospital to offer the services of such NPPs to be paid for by the physicians on a fair market value hourly basis. Remembering that fair market value is a range and not a number, hospitals can employ these individuals and lease them to the community-based physicians who can then, completely within the boundaries of the fraud and abuse laws and Medicare reimbursement rules, bill for their services at 85 percent of the Medicare Physician Fee Schedule or even at 100 percent when the services are "incident to" the physician.¹ This automatically creates legitimate revenues for the physicians and bonds them with the facility.

Imagine if these NPPs were specially trained in the diseases subject to the most regulation, pay for performance and performance measurement initiatives, such as diabetes and congestive heart failure, so that these personnel could help physicians standardize themselves. Suppose further that they were trained as trainers as well as extenders.

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¹See Gosfield, "The Ins and Outs of Incident To Reimbursement," *Fam Practice Mgt.* (Nov./Dec. 2001), pp. 23-27, <http://www.aafp.org/fpm/20011100/23thei.html>.

Together, this approach which directly benefits the physicians in their wallets, could also help them be positioned for the new world of report cards and pay for performance. Suppose still further, that these personnel also facilitated clinical integration among the physicians to whom they related, all while remaining employees of the hospital and getting the advantage of its fringe benefits and collegial environment. This is truly a win-win.

Another version of the same approach would take advantage of the Medicare rule that allows NPPs “in the same practice” as the physician to round on the patients at the hospital, performing significant and substantive clinical services. The physician is then permitted to go over later in the day, and so long as he has any face-to-face encounter with the patient during which time he performs any portion of the visit, then the entire visit, including the NPP’s services, can be billed at 100 percent of the Medicare Physician Fee Schedule.² The NPP becomes “in the same practice” as the physician by virtue of his leasing the NPP from the hospital, even if only for an hour or two at a time.

The point is that the technique is flexible, could be applied by hospital departments (*e.g.*, the cardiology or oncology trained NPPs) or by cross-disciplinary disease states (*e.g.*, the geriatric or pediatric NPPs, or the breast center NPPs) providing services to different types of specialists all involved in treating the same patient from different specialty perspectives. All of this is entirely legitimate under all the federal fraud and abuse and reimbursement rules and could significantly advance the physician’s state of the art of quality performance and efficiency.

§ 5:23 Physician recruitment for quality

The Stark Phase II regulations also, mercifully, recognized that many physicians do not want to be recruited to set up a solo practice in a far away community (one of the recruitment requirements) nor do many want to be direct hospital employees. Therefore, it is now legitimate for a hospital to provide recruitment support to a physician practice already referring to them, subject to a number of conditions. Support

²Transmittal 1776 (Oct. 25, 2002), amending § 15501B of the Carrier’s Manual, Pub. 100-4, Claims Processing Manual 12-§ 30-6B.

can only be offered for the incremental cost of adding the new physician, as well as an income guarantee, but that money must be paid directly to the recruited physician, even if other support is made available to his employing group. Without focusing on the other restrictions in the exception, including that the group may not impose a restrictive covenant on the new physician during the term of the hospital's support,¹ this exception could also offer some possibilities to facilitate the advancement of the existing practice on the quality pathway.

The hospital could work with a critical group practice to recruit a new physician to work there, following all the typical and regulated requirements associated with such recruitment. But the hospital could also pay him fair market value compensation on a part-time, time-limited basis, to help the hospital with those of its quality initiatives that would benefit from critical physician support. If he were also taught how to train others in these initiatives, that physician, working with the host group, could help them improve their abilities to change their practices in relationship to the hospital. This would, at the same time, subsidize the new physician in the community in a legitimate way, advance the hospital's quality mission during the term of the physician's quality-relevant duties (thereby obviating the need to repay that money which is simply compensation and not a guarantee), and further have the potential for sustained improvement at the end of his tenure, by virtue of his being in a position to better advance his new practice group's attention to quality issues both within its four walls and in relationship to the hospital.

V. PLANS HELPING PHYSICIANS

§ 5:24 Generally

Acknowledging the current tensions between hospitals and physicians, relations between physicians and managed care plans ("MCOs") have been even more contentious over the years. Resentment over payment controls, lowered reimbursement and increased administrative demands have soured the connections between plans and physicians as

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¹42 C.F.R. § 411.357(e).

their significant others. Yet, the law is far less a barrier to better collaborations for quality here than in the hospital-physician dyad because physicians do not “refer” in the fraud and abuse sense to a health plan. Apart from rules pertaining to incentives which may not encourage physicians to skimp on care¹ this aspect of the quality context has not gotten much attention from regulators. Therefore, with managed care plans today frequently on the defensive with regard to their programs and effects, and considerable consolidation in the industry which further fuels physician resentment,² health plans which position themselves better with physicians will, in the long run, be more successful than those which gather their enmity.

§ 5:25 Clinical integration

The rationales for clinical integration are often cast from the viewpoint of the antitrust issues when physicians bargain with health plans for higher reimbursement. And that is certainly a prime reason to clinically integrate that gets physicians’ attention. But the real reasons for physicians to clinically integrate turn on the fact that to be successful in the new environment they need to have meaningful information to compare what works and what does not work for physicians in their specific type of practice setting to produce good clinical results for patients and more efficiency in delivering care. It is virtually impossible for this type of analysis to be conducted when physicians remain in very small practices where they do not interrelate with their colleagues on these points. If MCOs were to facilitate the clinical integration of otherwise unrelated physicians, it would only redound to the plan’s benefit as well as the physicians’.

The role of health plans as true infomediaries for physicians—providing them with useful, valid, actionable data to

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¹42 U.S.C.A. § 1395nn(e)(3)(B); 42 U.S.C.A. § 1395w-22(j)(4). *See also* Gosfield, “Making Quality Happen: In Search of Legal Weightlessness,” *Health Law Handbook* (A. Gosfield, ed. 2002).

²*See, e.g.*, among the most recent manifestations “AMA calls on Attorney General to Investigate United Health Group acquisition of Pacificare Health Systems” (July 25, 2005), <http://www.ama-assn.org/ama/pub/category/1534B.html>.

help them improve their performance clinically and economically—is one which has not evolved with reference to assisting the physicians as a primary goal. Moreover, physicians have been highly critical of the legitimacy of plan data maintained about them. This aspect of plan-physician relationships is one in which the plans have repeatedly positioned themselves to meet their own needs rather than taking as the driving force how to help the physicians. Given the spectacular dependence of plans on physicians this limited view seems counterintuitive at best. All of the same principles of engagement set forth in § 5:12 with respect to hospitals are just as meaningful in plan-physician relationships. Clinical integration can serve as a lever to a very changed dynamic. The reasons for physicians to clinically integrate are oriented around quality. From the plan's point of view, to the extent clinical integration empowers physicians to bargain for better rates for better care, at least that negotiation would come from a far better place than physicians simply demanding more money because they want it.

§ 5:26 Information technology support

Because they are not implicated in the same way by Stark statute proscriptions, some plans actually already have moved into the arena of donating to physicians technologies they can use in delivering care more efficiently. The proposed regulations specifically approve such donations by plans offering the Medicare prescription drug benefit as well as Medicare Advantage plans. Electronic health records and e-prescribing opportunities for plans to help physicians are now explicitly articulated as opportunities for collaboration, but some plans have gotten there on their own.¹ Fallon Community Health Plan has provided a grant to the Central Massachusetts Independent Physician Association, the largest independent group of private physicians in the greater Worcester, MA area, to permit it to give each of its 150 physician members up to \$5,000 for the implementation of

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¹“MCOs Use Financial Incentives, Partnerships to Boost MDs E-Prescribing Utilization,” *Managed Care Week* (May 9, 2005), http://www.aishealth.com/ManagedCare/GenBus/MCW_e-prescribing.html.

electronic medical records.² The newsworthy nature of this program, though, points to its relative rarity today. To note the potential synergies from physicians and the health plans to which they relate having interoperable electronic health records would seem almost too obvious to state; but the slow pace with which these initiatives are unfolding belies that assumption. To implement new ways of lessening the burdens on physicians, both financial and administrative, merits swifter implementation with more scale.

§ 5:27 Administrative burden reduction

A principal way in which health plans have tainted their relationships with physicians over the years has been in the administrative demands they impose for the health plan's purposes of medical management and cost control. From prior authorizations for hospital admissions and lengths of stay to now include prior authorizations of expensive imaging services,¹ to denying payment to physician groups for the services of legally qualified physician extenders and NPPs, to imposing formularies around which physicians must interact with additional administrative agents in the form of pharmacy benefit managers, along with their other administrative agents including managed behavioral health companies, imaging services managers, in addition to disease management companies. All of this combined with Medicare's separate administrative requirements is stealing time from the essential doctor-patient interactions which create good patient satisfaction scores and also improve the quality of care delivered. Physicians cannot long endure the exacerbation of these already intolerable demands when they are being paid less and less.

If plans were to provide useful, accurate information on which physicians could actually take action to improve their care, if plans were to help them develop such skills and techniques rather than to simply impose payment and ser-

²"Doctors Receive Grants from Largest Worcester-Area Physicians' Group to Develop Electronic medical Records and Improve Quality of Care," <http://www.fchp.org/news/press/PressRelease.aspx?cid+1250>.

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¹See, e.g., <http://www.americanimaging.net/services/utlization/utlization.html>, describing the services of American Imaging Management, Inc.

vice denials, the need for all of the inspection and cross-checking programs which have proliferated over the years would diminish. The application of five fundamental principles in plan-physician interactions would affirmatively assist physicians and would considerably advance the business case for both them and their plan significant others.² (1) Help physicians standardize their care processes and service delivery techniques to the evidence base and provide them tools to help them do so; (2) simplify the administrative context and siloed management programs with which they must contend; (3) use clinical relevance as the touchstone for all physician-relevant activities and programs (“does this initiative advance the ability to deliver evidence-based medicine and not add time demands to the physician’s day?”); (4) assist physicians to engage patients around the evidence base of care and the patient’s responsibilities in obtaining care; and (5) fix accountability in report cards and other public statements at the locus of accountability. The implementation of these principles broadly, deeply and as over-arching driving forces in plan-physician relationships would considerably improve the tainted quality of their interactions today. None of them triggers any regulatory exposure. All can be effected within the current environment where there is a will to collaborate for common quality purposes.

§ 5:28 Reformed payment

Perhaps the most significant barrier to real advancement in quality has been the payment systems plans offer to physicians. Fee for service payment incentivizes physicians to overuse and accretes the administrative burdens they must suffer. Capitation drives toward underuse and still has not significantly mitigated the administrative load. A new approach to payment dubbed **PROMETHEUS** for **P**rovider **P**ayment **R**eform for **O**utcomes, **M**argins, **E**vidence, **T**ransparency, **H**assle reduction, **E**xcellence, **U**nderstandability and **S**ustainability would pay providers a negotiated rate for what it costs to deliver the science in an agreed upon clinical practice guideline (“CPG”)—an evidence-based case rate (“ECR”). Designed by a group of experts from a range of

²See Gosfield and Reinertsen, “Doing Well by Doing Good: Improving the Business Case for Quality” (June 2003), <http://www.uft-a.com>.

disciplines, including this author, the notion is that this system would create considerable flexibility in the payment environment, while anchoring payment to science.

Providers—physicians and all others—who choose to participate for the conditions for which they seek this type of payment, would negotiate with plans to be paid a case rate to treat the patient in accordance with the guideline across a time continuum. The bulk of the rate would be paid prospectively in accordance with that aspect of the care which the relevant provider or provider group chose to bargain for and delivered. Hospitals might join with physicians; otherwise competing specialists might come together to bid for care; integrated delivery systems could bid for the entire continuum of care including all elements of care including physicians, hospitals, laboratories, pharmacies, skilled nursing, home health and more.

Ten percent of the bargained-for payment would be held back to evaluate whether the care bargained for was delivered. This judgment would be based on a comprehensive scorecard that would assess whether the salient elements of the CPG were provided, the patient's perception of the experience of care, and, for physicians not in an integrated delivery system, about 30 percent of their score would reflect the efficiency and quality of the other providers treating the patient for the same condition. Those who score well would receive the remaining 10 percent and those who do not score well would not get the remaining 10 percent payment. In between, payment would be pro rata reflecting that provider's score. ECRs are risk adjusted to reflect co-morbidities in patients.

The design of the system is specifically intended to reduce administrative burden to physicians. Because of the agreed upon payment linked to the CPG, there is no need for prior authorizations of admissions or lengths of stay. The system is indifferent to the level of visit rendered and therefore there is no need for physicians to waste time documenting evaluation and management codes, obtaining or issuing prior authorizations for durable medical equipment, physical therapy or anything else included in the CPG. The mechanisms of PROMETHEUS are intended to be completely transparent to the payors, the plans, the providers, the consumers and the patients. How the payments are constructed, the results of the scorecards, the techniques of risk adjustment—everything is open and available to all players.

Plans that adopt such a payment system would, by virtue of that change alone, advance the quality of care they offer to their subscribers while they bonded the physician network to them. This represents a major change in the most significant obstacle to true leaps forward in health care quality. There is much to be learned from piloting the model which will begin in the first quarter of 2007.

VI. CONCLUSION

§ 5:29 Generally

The demands for improved quality are ubiquitous in health care. For all the glorious capabilities of the American health care system, it is apparent that swifter improvement in the care it provides is not only possible, it is necessary. Toward this end, the role of physicians is key and merits new focus. To make more rapid and substantial change, the real question is how to achieve what is now required, taking into account the disparate pressures on the three principal parties to the lion's share of health care processes and outcomes—physicians, hospitals and health plans. It is time for all three to recognize where their common business interests intersect with the quality mission.

With the new emphasis on transparency, evidence-based medicine, performance measurement, pay for performance, and new forms of liability, the health care world is at a singularly propitious moment for this fundamental task—to rethink what have been hidebound, fairly rigid and even when creativity is sought, relatively narrowly conceived relationships in favor of more collaborative undertakings. As we have seen here, the law is not only not an impediment to many initiatives with substantial potential to propel quality in new, more rapid and different ways, sometimes with improved understanding of its significance, as with clinical integration, the law can actually be a boon to these long desired but perpetually elusive goals.

The fundamental mission of the health care enterprise is straightforward—to deliver high quality care to people who need it at reasonable cost. Accomplishing it is more likely where the parties work together in as many ways as possible.