

Chapter 13

Making Quality Happen: In Search of Legal Weightlessness

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§ 13:1 Introduction

The contemporary moment in health policy is nothing

¹The author is the Chairman of the Board of the National Committee for Quality Assurance (NCQA), but the opinions expressed here are exclusively her own and should not be imputed to NCQA in any way whatsoever.

short of a Dionysian rhapsody of regulation, the inhospitality tradition gone riot, the formal and final enshrinement of the doctrine that everything not mandatory is prohibited.¹

Although the hysteria of free-marketeers about most regulation in health care often merits discounting as mere hyperbole, nowhere is the paralyzing weight of health care regulation more evident than in the disconnect between what is necessary to make real improvements in health care quality and the crushing burden of the regulatory constraints on doing so. The clarity of this paradox is even more dramatic when we consider that much of the difficulty stems from regulation which claims to be aimed at bolstering quality or at least appropriateness of care.

Imagine the following health care market:

Physicians are paid based on how well they hew to evidence-based clinical practice guidelines (CPGs) and research protocols. For services which conform to the selected CPGs, there is no requirement for prior authorization, concurrent review, or post-payment utilization review. Centers of excellence perform extremely risky, complex procedures, so not all physicians and facilities provide all services. At the same time, research protocols are used to develop expertise in other settings when clinical trial safeguards are strictly applied. Apart from quality controls for market entry (*i.e.*, credentialing, licensure, and threshold quality standards to provide certain services), no one worries about the financial relationships between physicians and the entities which serve their patients.

Once a guideline is agreed to, payors, including Medicare, occasionally render post-payment audits on reasonable samples, simply to determine that guidelines are being followed. Payment systems include (1) case rates where a single payment is made for treatment of

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¹Robinson, "Theory and Practice in The Design of Physician Payment Incentives," 79 *The Milbank Quarterly* 149, 174 (2001).

a specific condition for a defined period of time, and (2) payment based on quantification of expected fee for service payments, but all systems reflect CPGs. Other options are available if proposed in a collaborative construct among the providers and payers. Financial risk is taken, if at all, at large group and system levels which involve more than one physician.

In some instances, otherwise competing physicians join in clinically driven virtual organizations which standardize care in accordance with guidelines, measure performance in accordance with those standards, and actively seek to improve care and take action against participants who cannot effectively change their behavior. Within physician groups and organizations (including where hospitals employ physicians), the physicians' compensation reflects guideline conformity and the strength of their doctor-patient relationships measured in terms of customer satisfaction surveys and patient perception of care. Payors and health plans reward systems and physicians that excel in their quality performance and patient relationships.

Hospitals work with the physicians to provide care consistent with those guidelines and pay them for work they do which benefits the hospital directly, whether (a) through traditional "gainsharing" concepts to motivate workers, or (b) for consultant services necessary to maintain the hospital's programs, whether provided by physicians or others. At the delivery system level, the facilities and physicians collaborate to safeguard the clinical validity and dynamism of the application of the guidelines and research protocols which are the bedrock of the system.

Hospitals design their manpower recruitment planning around the CPGs. Care teams are the core model for delivering care and are taken into account in the vehicles (*e.g.*, medical staff bylaws) by which clinicians obtain the opportunity to render services within a facility setting. There is relatively little emphasis on which type of licensed clinician performs specific tasks. Human resources are assigned so the best qualified indi-

vidual in the moment works to meet the patient's needs coupled with a philosophy to use personnel at their highest and best use.

Hospitals develop and support clinical leaders for quality, oriented around implementing CPGs throughout the enterprise. Workflow, information technology and sharing, capital budgets and organizational structures are driven by CPGs and the clinical needs of the patients rather than by tax laws, cost accounting and siloed information needs. Hospitals freely share information with and among physicians in the interests of quality improvement. In addition to patient-specific treatment data, to which clinicians have access for quality improvement purposes, clinicians and others at all levels of the system report untoward incidents and errors to a closed database which is used to study and improve clinical and system performance.

Ancillary providers—durable medical equipment, rehabilitation, home health and pharmacy providers—are included in the treatment continuum and have access to patient data as relevant to their needs to provide their services, in accordance with the applicable CPG. Neither they nor the hospitals themselves are subject to prior authorization or concurrent review once having agreed to provide care in accordance with explicit clinical pathways.

Health plans not only manage clinician and provider credentialing and pay for services, they participate in local efforts to improve care, by facilitating implementation of CPGs and research protocols. Their vetting of providers (hospitals, physicians and others) turns on explicit, agreed upon standards. They report performance of the systems and physicians to the public according to the activities for which each controls; in other words, physicians are measured for their knowledge of their clinical craft and their doctor-patient relationships. Clinical outcomes and system guidelines conformity is reported at the system level. Plans manage early detection, disease management and public reporting programs, in collaboration with providers.

They develop specific tools to permit bench marking and best practices models to evolve and facilitate their implementation within their networks. All the parties benchmark their performance against those of their peers. The results are used to revise CPGs and to change processes to conform with what the data shows are best practices thereby renewing and maintaining the vitality of the processes and standards used throughout.

While not available for all conditions or in all settings, for those physician groups, hospitals, systems and plans which (1) explicitly agree to be evaluated by independent auditors/accreditors to validate that they have a quality-driven infrastructure, (2) participate in broader information sharing to a closed clearinghouse on errors so more participants can benefit from lessons learned, and (3) commit to public performance reporting, an alternative compensation system for tort is available.²

A utopian view of millennial health care? Not necessarily. Likely the market described is not even ideal and the description certainly is not a complete picture of what would be necessary to perfect a model of clinical quality and payment. But much of what is described in the scenario above is achievable and in many ways reflects the principles set forth in the landmark study *Crossing the Quality Chasm*.³ There is no question, though, that the relationships and functions it describes are so far from today's reality in most settings, that even partial movement toward the world described would create a far more clinically relevant, quality focused health care system. It would, in fact, begin to create an actual system with consistent principles of action which drive the major players and which emanate from certain core values.

²Gosfield, "Liability for Quality: A Modest Proposal," *Managed Care & Cancer* 11-12 (Jan./Feb. 2000).

³Corrigan, et al., National Academy Press (Washington, D.C., 2001).

To the extent that significantly improved quality of health care has proven elusive over the last twenty-five years, it has not been mere lack of will that has prevented real change. It must be acknowledged that there are many disparate factors which undermine and thwart transformation or even incremental transition to simpler, more standardized, more clinically relevant systems and programs which are more responsive to the real concerns of patients, policy-makers, payors and physicians. To tackle the practical implications of change though, there should be clear recognition that the doctor-patient relationship is the essential portal to the rest of the system.

The critical role of physicians cannot be overstated. Patients enter the system through a doctor-patient encounter, and physicians drive the delivery of all other services. The Institute of Medicine has said that “Transferring knowledge is care.”³ The essential role of physicians is to “transform information into meaningful explanations of the present, predictions of the future and changed futures, mainly for individual patients and sometimes for whole populations.”⁴ Whatever impedes the application of standardized science to care and limits the strength of the primary relationship through which knowledge can be transferred and healing can occur will stifle real quality improvement. To move markets more toward the scenario above, lawyers, policymakers, and those in the system with the will to make a difference will have to take into account the regulatory environment which stands in the way of meaningful leaps forward, with particular emphasis on barriers to deeper, more effective doctor-patient relationships.

This article scans and elucidates some of the more obvious legal and regulatory issues which are contained

³Corrigan, et al., National Academy Press, 72 (Washington, D.C. 2001).

⁴Reinertsen, “Health Care: Past, Present and Future,” *Group Practice Journal* 37-43 (March/April 1997).

in the scenario, focusing on their implications primarily as they relate to physicians. The operational barriers to broad scale change in any community are manifold and present their own challenges; but they are beyond this consideration. To create a truly quality-relevant environment, many changes at organizational, structural, dynamic and other levels will have to be adopted. Here, I consider only salient legal issues with a focus on physician reimbursement and compensation, anti-kickback and anti-referral laws, HIPAA, and antitrust and clinical integration, to enhance an understanding of how the major existing legal barriers can be managed (and where wholesale revision is necessary), so quality can advance more in the direction of our hypothetical market.

§ 13:2 Reimbursement and Compensation

Many commentators have decried the fact that typical existing payment systems neither reward nor even motivate quality.¹ Capitation has been touted as a system which at least drives toward prevention and early detection;² but other observers have posited that capitation reflects nothing about clinical necessity or quality and its incentives are so blunt and broad as to undermine medically necessary care.³ Percent of premium risk contracts pay to the provider just that—

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¹Corrigan, et al., National Academy Press Ch. 2 (Washington, D.C. 2001), and Becher and Chassin, “Improving Quality, Minimizing Error: Making It Happen,” *Health Affairs* 68-81 (May/June 2001).

²California Association of Health Plans, Issue Briefs, “Capitation and Quality in Health Care,” 4/97, http://www.calhealthplans.com/ib_capitation_quality.htm; for an excellent analysis of multiple forms of physician compensation and their pitfalls, see Robinson, “Theory and Practice in The Design of Physician Payment Incentives,” 79 *The Milbank Quarterly* (2001).

³Court, “HMOs’ Gestures Won’t Solve Patient Care Problems,” San Diego Union-Tribune (July 12, 2001), <http://www.consumerwatchdog.org/healthcare/nw/nw001779.php3>; a settle-

percent of the premium, so these payment systems incorporate inherently all of the disadvantages of actuarial judgments, that is, an analysis of past behavior projected forward based on certain demographic and epidemiological assumptions which may or may not reflect clinical appropriateness, let alone quality. Episode of care (EOC) reimbursement⁴ and its variants such as contact capitation⁵ contain essentially both the same incentives and pitfalls as pure capitation models.

As capitation has come under increased skepticism in the sweep of managed care backlash, fee for service payment systems have returned in some quarters⁶ and never left in Medicare. To shift any market in significant ways, the influence of Medicare reimbursement must be confronted, too.

§ 13:3 —Medicare Physician Payment

As of 1992, Congress provided that Medicare payment to physicians must be made on the basis of a fee schedule which takes into account relative values of

ment between the Texas Attorney General and Aetna was seen as a major blow to capitation and its analogues—withholds and limited specialist referrals. Klein, “Aetna consents to physician contracting principles in Texas,” *AMNews* (April 24, 2000), http://www.ama-assn.org/sci-pubs/amnews/pick_00/gv110424.htm.

⁴See Krane and McNair, “Episodes of Care Overview of Legal and Regulatory Issues,” *Health Law Handbook* 423 (Gosfield, ed. 2001).

⁵Robinson, “Theory and Practice in The Design of Physician Payment Incentives” 79 *The Milbank Quarterly* (2001), and Frank, “Contact Capitation for Specialists: Can the Pie Be Divided More Fairly?” 5 *Cost & Quality* (June 1999), <http://www.cost-quality.com/5,2art3.html>.

⁶Carlson, “Physician Financial Incentives: Another UM Tool Bites the Dust,” *Managed Care* (June 2000), <http://www.managedcaremag.com/archives/0006/0006incentives.html>; and Jacob, “PacifiCare Hopes to Regroup Financially in Colorado,” *AMNews* 20-23 (April 2001), http://www.ama-assn.org/sci-pubs/amnews/pick_01/bisc0423.htm.

services measured against each other, multiplied by a conversion factor.¹ The statute further requires a uniform coding system which takes into account all physician services.² By regulation, the Secretary of Department of Health and Human Services (“DDHS”) has adopted the American Medical Association’s (“AMA”) nomenclature, the Common Procedural Terminology (CPT).³ Unfortunately, one of the strongest barriers to the ability of physicians to focus on quality, spend more time, and deepen their relationships with patients is the required documentation of both the scope of services rendered along with some manifestation of their medical necessity. Some of the requirements are local carrier policies which set forth their interpretations of national policy including, for example, which diagnostic code (ICD-9) must be used, thereby forbidding physicians to code the patient’s signs and symptoms when a diagnostic service ordered to evaluate the patient’s needs demonstrates an abnormal result.⁴ By statute, failure to put the diagnostic code on a claim is subject to a \$2000 civil money penalty.⁵ With the advent of evaluation and management codes (E&M codes) created to quantify the cognitive effort associated with non-procedural encounters between clinicians and patients, new documentation guidelines were estab-

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¹42 U.S.C.A. § 1395w-4.

²42 U.S.C.A. § 1395w-4(c)(5).

³56 Fed. Reg. 59,506 (Nov. 25, 1991); *see also* 42 C.F.R. § 415.40 (2002) in which HCFA reserved to itself the right to establish uniform national definitions of codes and modifiers even as it adopted the AMA’s CPT designations for the bulk of physician services paid for on the then newly established fee schedule.

⁴*See, for example*, “ICD-9-CM Coding for Diagnostic Tests,” Illinois Michigan Medicare Part B Bulletin (Nov. 2001).

⁵42 U.S.C.A. § 1395u(p).

lished and then refined further.⁶ Local carrier applications vary around the country.⁷

The legal perils in the combined weight of these multiple requirements lies in their link to post-payment utilization review and ultimately to false claims liability. In its Semi-Annual Report for 2001, the Office of the Inspector General found inappropriate or erroneous fee for service payments in the amount of \$11.9 billion during fiscal year 2000. Unsupported and medically unnecessary services continued to be the pervasive problems.⁸ Although these numbers regarding failure to document services effectively are noteworthy, physician complaints about the time it takes to document just the E&M services have escalated:

The current guidelines emphasize the clerical skill of physicians and do not reflect the intensity of the physician service. They clutter the medical record with unnecessary verbiage, interfere with physician-to-physician communication and waste precious physician time. In addition, while HCFA and the AMA maintain that these are only guidelines, it is clear that the government will use them as a basis in fraud investigations.⁹

The AMA reportedly has survey data showing that physicians spend one hour completing Medicare forms and meeting administrative requirements for every four hours of patient care.¹⁰ The administrative burdens have become so great, that fewer physicians in fee for

⁶“Documentation and Evaluation Guidelines” (1995) and (1997), <http://www.hcfa.gov/medlearn/emdoc.htm>.

⁷See <http://www.lrmp.net> for a listing of carrier policies for payment, including documentation of services.

⁸OIG SemiAnnual Report 2 (Oct.-Mar. 2001), <http://oig.hhs.gov/semann/01ssemi.pdf>.

⁹American College of Cardiology, Evaluation and Management Documentation Guidelines, http://www.acc.org/advocacy/advoc__issues/emwebsite.htm.

¹⁰Qian, Bureaucratic Malpractice, *The Business of Health*, An NYU School of Journalism Special Report (May 1, 2001), <http://journalism.fas.nyu.edu/mag/boh/qian.htm>.

service medicine are accepting new Medicare patients, with some communities finding that only 34% of physicians will do so.¹¹ Studies now show that clinical oncologists are spending, on average, more than four times the time in documenting care and completing paper work than twenty-five years ago.¹²

Those dilemmas pertain only to whether the data recorded in the medical record substantiates the scope of the service performed. Another problem for physicians is that there is no generalized source for standards of medical necessity. They are not listed. They are not published. There are not even normative parameters made available to physicians on an ongoing basis.

The Peer Review Organization (“PRO”) program was originally supposed to make medical necessity judgments for inpatient, outpatient and physician care, based on norms, criteria and standards; but its orientation has been regulatorily reoriented so much and so often over the last two decades, that the statute and the implementing operational requirements seem to be from two different worlds. Although the statute calls these entities “Utilization and Quality Control Peer Review Organizations,” the Secretary of DHHS in the latest pronouncements on the subject has now dubbed them QIOs, “Quality Improvement Organizations,” which will have a major focus on nursing home care.¹³ Today, the program has little impact on physicians, unless they engage in grossly flagrant violations of stan-

¹¹Qian, Bureaucratic Malpractice, *The Business of Health*, An NYU School of Journalism Special Report (May 1, 2001), <http://journalism.fas.nyu.edu/mag/boh/qian.htm>.

¹²American Society for Clinical Oncology, Excessive Paperwork Taking Away from Cancer Patient Care, Professional Mentoring and Research (May 12, 2001), Annual Meeting News Room, <http://www.asco.org/people/nr/html/01/ex.htm>.

¹³Lovern, “QIOs: Eye Mission: Better Reporting,” *Modern Healthcare* 12 (Dec. 10, 2001); Lovern, “Gotcha Gives Way to Guidance,” *Modern Healthcare* 20 (Dec. 17, 2001).

dards or fail in a substantial number of cases substantially to conform with a PRO's standards.¹⁴

In Medicare generally, the determination of medical necessity of the physicians' services is made only in post-payment audits for physicians who are identified on the basis of data aberrancies or beneficiary complaints and thereafter on prepayment review for a physician targeted as problematic.¹⁵ Therefore, whether any physician will be subjected to audit is unpredictable; so all must expend the same energies, lest they end up in the snares of the enforcers. None of these payment mechanisms reflects any explicit quality standards, parameters, protocols or guidelines.

As for direct recognition of quality, during 2001, some managed care payors have publicized their efforts to reward quality and pay physician groups more money based on their quality performance. Some define quality as achieving specified targets.¹⁶ Some reference patient satisfaction.¹⁷ Still others target those HEDIS¹⁸ measures which focus on services provided by physicians.¹⁹ Medicare fee for service is still only contemplating a move in that direction with the

¹⁴42 U.S.C.A. § 1320c-5; 42 C.F.R. §§ 1004.30 et seq. (2002). For a discussion of the evolution of the PRO program *see* Gosfield, "Utilization Management, Quality Assurance and Practice Guidelines," *AHLA, Health Law Practice Guide* 25-1 to 25-78 (2001).

¹⁵*See* 4.0 et seq., and *Medicare Program Integrity Manual* Ch. 2, http://www.hcfa.gov/pubforms/83_pim/pim83toc.htm.

¹⁶Aquilina, "Buyers Reward Physicians for Quality" (Feb. 2001), http://www.qiphysician.com/cgi-bin/article.cgi?article_id+885.

¹⁷Jackson, "California HMO: Doctor Bonuses Based on Patient Satisfaction," *AMNews* (July 30, 2001), http://www.ama-assn.org/sci-pubs/amnews/pick_01/bil10730.htm.

¹⁸*Health Plan and Employer Data and Information Set*, published by NCQA.

¹⁹Eaton, "Health Plans Rewarding Doctors for Meeting Quality Standards Rather Than Controlling Costs," *Managed Care Report, Physicians Financial News* (Sept. 30, 2001), <http://www.pfnpublishing.com/quality.htm>.

expectation that eventually Medicare payment will reward higher quality.

To change such a cumbersome and clinically irrelevant payment system, whether it is applied only in Medicare or, as is often the case, in private, commercial contracts too, is potentially the most critical step to radically reorient to an explicit quality-driven model how care is provided in this country. The physicians' stakes in the current context are far more appreciated today than ever before. The furor that met the government's efforts to revise the E&M documentation standards in 1998 was so intense, that those standards were pulled and have not yet been reissued.²⁰ The inability of the regulators to craft something which speaks meaningfully to physicians, even after all the complaints about the 1997 standards, underscores the need for a new conceptual framework. *Crossing the Quality Chasm* made it clear that new payment methods would need to be tested and piloted if quality is to advance. The Medicare statute already provides that money is available to develop and engage in experiments and demonstrations to determine whether other methods and approaches, could enhance efficiency and utilization "including a change to methods based on negotiated rates, [and] . . . would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services."²¹

²⁰See, for example, "New E&M Guidelines Postponed Indefinitely by HCFA," San Bernardino County Medical Society, *The Bulletin* (June 1998), <http://www.sbcms.org/southcalphysician/articles/art6c-98.htm> for an understanding of the absurdity of those guidelines see "How to Use the New E/M Documentation Guidelines," *ACP-ASIM Observer* (Nov. 1997), <http://www.acponline.org/journals/news/nov97/newem.htm>.

²¹42 U.S.C.A. § 1395b-1.

§ 13:4 —A New Approach

Imagining further our hypothetical market, consider what would happen to the amount of time physicians could spend with patients if we were to dramatically simplify the requirements for documentation of office visits by making payment based on delivering services explicitly in accordance with an agreed upon CPG. CPGs offer a new and potentially far simpler approach to documentation for payment. For example, in the treatment of congestive heart failure (“CHF”), a good CPG, such as the one published by the Institute for Clinical Systems Improvement,¹ sets forth the clinical symptoms which lead the physician to suspect CHF and then enumerates the components of a comprehensive initial evaluation. Whether the treating physician is the attending physician or a consultant, the visit code is easily determined. The guideline states the extent of the history to be reviewed, the scope of the physical examination to be performed, and the diagnostic testing to initiate—all the required elements for E&M coding. The guideline itself states the medical necessity for all the tests, based on clinical evidence. The complexity of the clinical decision-making is apparent from the application of the guideline’s terms, and need not entail documentation of irrelevant negative findings which make no difference in the patient’s treatment at all. Where the patient has other co-morbid conditions such as hypertension or diabetes, those clinical guidelines are referenced and also brought into play.

Evaluation of the test results with the patient, determination of an appropriate pharmacologic regimen and patient education are all included in the guideline and justify additional office visits which a physician practice can template with expected, applicable procedural and diagnostic codes. Steps to on-going evaluation of the effectiveness of outpatient therapies (using diagnostic

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¹ICSI “Health Care Guideline: Congestive Heart Failure in Adults” (Nov. 2000), <http://www.icsi.org/guide/CHF.pdf>.

testing and doctor-patient interaction) with appropriate adjustments in response, when to hospitalize, when to refer to subspecialists, and when to consider revascularization are all set forth. All of these translate into applicable CPT and ICD-9 codes.

A physician practice willing to commit explicitly to treat CHF patients in accordance with such a guideline could be paid, even by Medicare, for the agreed upon range of CPT codes, depending on the course of the patient's condition. Once agreed to, this technique would obviate the need for the physician to articulate in lengthy documentation the negative findings in the physical exam or the medical necessity of the service provided, merely to justify payment. A payer adopting this system might legitimately seek to conduct limited post-payment audits to assure that the guideline, in fact, was the basis for treatment, but this methodology would free significant physician time spent in writing data which has no bearing on treatment but is created purely to satisfy anticipated potential post-payment fraud audits.

If Medicare were to adopt or even endorse such an approach, physicians using it would see their liability for false claims based on underutilization, overutilization or misutilization virtually disappear.² The risk of exclusion based on quality failures would also evaporate. PROs would focus their energies on other than those physicians because the carrier acceptance of the CPG payment system would be binding on the PRO.³ Although a totally new approach to payment and documentation would be preferable, until policymakers and regulators can see their way clear to sweeping reform, at least the approach in our hypothetical market can be crafted to accommodate the existing legal

²For a discussion of existing fraud and abuse liabilities which sound in quality issues see Gosfield, "Legal Mandates for Physician Quality: Beyond Risk Management," *Health Law Handbook* 285-322 (Gosfield, ed. 2001).

³42 C.F.R. § 476.85 (2002).

mandates without perpetuating their administrative lunacies.

In commercial insurance, as distinct from Medicare, precisely the same technique could apply. Agreed upon CPGs, collaboratively selected by the plan or payor and the physicians, provide a basis for the physicians to provide care from a unitary and explicit clinical platform. Where the private context and Medicare are consistent, the inevitable result would be to not only make the physicians' lives simpler by not having to engage in documentation which serves neither a clinical nor a healing purpose, but also to make gathering data about care simpler. In reviewing their conformity to a CPG, physicians would then find it easier to identify opportunities to be more efficient and improve their processes. The roles of others—both clinicians and providers—indelivering care would be more clearly delineated.⁴ Plans would have better, more explicit data on which to evaluate and motivate their networks.

There are communities in which multiple payors are beginning to agree to use explicit and common CPGs.⁵ While science ought not be local, and Medicare is a national insurance program, where clinicians in a community seek to apply collaboratively selected guidelines (which meet the attributes for good clinical practice guidelines as enunciated by the Institute of Medicine in its earlier guidelines study)⁶ to provide the basis for payment, Medicare could permit such a mechanism

⁴To the extent the Medicare hospital payment system were coordinated, the more powerful the whole undertaking would be. DRGs are not based on CPGs, though, they are based on historical resource utilization patterns, no matter whether good or bad in terms of clinical quality. Even so, hospitals and physicians working together can apply CPGs within DRGs and some already do so.

⁵See "Minnesota Health Plans and Physicians Create a National" Minnesota Model "For Improving Health Care," Press Release, McHugh Communications Inc. (Mar. 13, 2001).

⁶*Clinical Practice Guidelines: Directions for a New Program*, National Academy Press 59 (Field and Lohr, ed., Washington D.C., 1990).

under a pilot methodology until proof of the concept is clear. Still further, this approach requires physician self-discipline and internal practice mechanisms to support its application. Not all physician groups can or need adopt it. Although the Medicare statute adopts the fee schedule as the foundation for fee for service payment, it does not require uniform application of it.

Today, quality payment from plans and insurers to physicians and groups only go so far. Moreover, when the payment increment for quality varies from 5% of the capitation payments to \$.30 per member per month for excellent performance⁷ one inevitably asks how much changed behavior these bonuses can stimulate when they are layered on top of basic payment systems (e.g., fee for service and capitation) which have no specific quality or even clinical relevance.

§ 13:5 —Physician Compensation

Moving down to the next level of incentive, within groups and systems, there have been few physician compensation systems which directly reward quality performance. This is also changing and represents yet another focus to attend to in order to propel the quality agenda. Compensation mechanisms within groups, particularly in markets that are not totally dominated by managed care, have created virtually bi-polar physician incentives for patient throughput and physician productivity measured in volumes of revenue, while at the same time proclaiming the need for efficiencies and utilization constraints to safeguard capitation dollars. No wonder physicians feel buffeted.

Today, more physician groups are beginning to peg individual physician compensation to quality performance. Some groups look to patient satisfaction scores, staff and peer reviews, and utilization of preven-

⁷Maguire, "As They Struggle to Improve Quality, HMOs Try a New Incentive: Bonuses," *ACP-ASIM Observer* (June 2001), <http://www.acponline.org/journals/news/jun01/bonuses.htm>.

tive services to determine one-quarter of a physician's income.¹ Others link total compensation to specific quantifiable measures of multi-variate factors such as net medical revenue, reduced practice expenses, cost and utilization, quality of care and patient satisfaction. These types of programs, which typically involve primary care network compensation of individual physicians, limit base salaries to 65% to 75% of gross compensation with the opportunity to earn bonuses that may reach 35% to 40% or more of base salaries.² Overall, though, the shift to quality oriented compensation is new and the literature on its application, as with most physician compensation data, is surprisingly scant.³ Although in the recent days of managed care reform and backlash there has been considerable heat on the subject, a closer investigation reveals very little associated light. The basic implications for quality in fee for service payment versus capitation has itself barely begun to be studied.⁴ While the methods of payment from health plans to physicians and systems has been relatively little analyzed, the internal compensation techniques and their impacts on quality within physician groups, or even from employers to physician-

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¹Maguire, "As They Struggle to Improve Quality, HMOs Try a New Incentive: Bonuses," *ACP-ASIM Observer* (June 2001), <http://www.acponline.org/journals/news/jun01/bonuses.htm>.

²Holm and Lipsky, "Using Compensation to Improve Primary Care," *MGM Journal* 46 (July/Aug. 1999).

³See Andreae and Freed "A New Paradigm in Academic Health Centers: Productivity-Based Physician Compensation," 48 *MGM Journal* 44 (May/June 2001), and Forland et al., "Capitation, Salary, Fee-For-Service and Mixed Systems of Payment: Effects on the Behaviour of Primary Care Physicians" (Cochrane Review), from The Cochrane Library, Issue 4 (2001), <http://www.cochrane.org/cochrane/revabstr/ab002215.htm>.

⁴Miller and Luft, "Does Managed Care Lead to Better or Worse Quality of Care?" *Health Affairs* 7-25 (Sept./Oct. 1997), and American Association of Health Plans, Research Brief, "Quality of Care and Health Plans" (April 2000).

employees, has been virtually ignored in the research focused around health care financial incentives.⁵

As a matter of law, the physician employment contract is the primary legal determinant of physician compensation, as influenced by the common law of employment and ethical guidelines. In addition, however, state law issues including corporate practice of medicine doctrines can get in the way of approaches that could positively influence quality. These doctrines take as axiomatic that employment by definition entails direction of the employee, stemming from ancient principles of master-servant. It is, therefore, against public policy, so the doctrine goes, to permit non-licensed individuals or entities to corrupt the independent judgment of learned professionals—physicians.

In today's world, the validity of this principle when we are trying to establish collaborative, aligned mechanisms to create quality-driven environments is not only questionable, it leads to absurd organizational constructs designed to accomplish by economic indirection that which cannot be done directly. Captive professional corporations whose sole shareholders are 'friendly' with the business entity shareholders, independent contractor relationships between physicians and business entities, not-for-profit taxable membership companies, physician practice management companies or medical services organizations (MSOs) holding "sweep" accounts that gather all the money physicians receive for their services and then pay them back a salary equivalent, are all techniques which lawyers have developed to cope with these restrictions. Each creates its own outlandish organizational and operational realities to make the business work within the common law framework. This only adds to the complexity of health care delivery toward no quality end at all. Similar legal eccentricities result from certain statutes aimed at eliminating "improper" physician referrals.

⁵Robinson, "Theory and Practice in The Design of Physician Payment Incentives," *The Milbank Quarterly* 79 (2001).

§ 13:6 Anti-Kickback and Anti-Referral Laws

If the general regulation of health care is a stellar demonstration of the inhospitality tradition noted by Robinson—“That which cannot be understood without effort is deemed *ipso facto* to be designed for fraud, monopolization, or some other antisocial purpose”¹—then the anti-kickback and anti-referral laws are super novae of this thinking. These statutes date back to the Mesozoic-era equivalent in health care, with the anti-kickback statute from the Triassic period and the more recent Stark statute from the Cretaceous era. We can only hope that what we see today is the delayed light from their long ago flameout reflected in today’s regulatory environment, soon to extinguish completely. Until that happens, though, we must take into account the barriers their interpretation presents to our hypothetical market and the chances for improving quality.

§ 13:7 —Background

Their current obsolescence does not mean that when they were adopted these laws had no reasonable impetus. It is their current applications which highlight their irrelevance to quality. The general proposition that fraudulent acts under Medicare would be subject to penalty was enacted in 1972. The legislative history spoke of “penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the Medicare and Medicaid programs.”¹ At that time it was stated that the criminal penalty provision would include such practices as the soliciting, offering, or accepting of

[Section 13:6]

¹Robinson, “Theory and Practice in The Design of Physician Payment Incentives,” *The Milbank Quarterly* 173 (2001).

[Section 13:7]

¹Sen. Fin. Comm. Rpt. to H.R. 1, Social Security Amendments of 1972, 208.

kickbacks or bribes, including the rebating of a portion of a fee or charge for a patient referral involving individuals, providers of healthcare services, and business entities such as corporations, companies, associations, firms, partnerships, societies, and joint stock companies. There is no further elucidation on the prohibited practices in 1972. In 1972, the violations were to be treated as misdemeanors.

In 1977, the penalties were upgraded to felony status, and rewritten to clarify and restructure those provisions in then current law which defined the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid.² “The bill would define the term ‘any remuneration’ broadly to encompass kickbacks, bribes or rebates which may be made directly or indirectly, overtly or covertly, in cash or in kind.”³

Ten years later, in 1987, the Secretary of DDHS was given additional authority, requiring exclusion from Medicare and Medicaid of any individual or entity who has engaged in certain proscribed behaviors and permitting it in other situations. These authorities, along with considerably increased power to assess civil monetary penalties in the amount of \$50,000 for each violation were further extended in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and then even more so a year later in the Balanced Budget Act.⁴

So, the anti-kickback statute was designed to prevent what in the ordinary course of business would be understood to be kickbacks and bribes for referrals. It was clearly focused on cost, as stated in the legislative history. In its interpretation though, and likely to escalate since civil penalties do not require the government to meet the criminal burden of proof, the enforce-

²Sen. Fin. Comm. Rpt. to S.143, 10 (Sept. 26, 1977).

³Sen. Fin. Comm. Rpt. to S.143, 12 (Sept. 26, 1977).

⁴Subtitle A—Fraud and Abuse Control Program; Title XI of the Social Security Act. 42 U.S.C.A. §§ 1320b et seq.

ers have come to sweep into their ambit virtually any transaction in which there is an economic benefit of any kind that redounds to a physician coincident with his federal patient referrals. Although safe harbor regulations were intended to quiet the considerable anxieties of those in the industry regarding exactly how far the government intended to go, one need only peruse the anti-kickback issues alone in the omnibus summaries contributed by Sandy Teplitzky and Craig Holden over the fourteen editions of this Handbook, to learn just how canonical the government has become both in the breadth of its views of the statute's scope and the refined details of what relationships are protected either in safe harbor regulations or Advisory Opinions. We are well far afield from kickbacks and payments for referrals.

That statutory scheme notwithstanding, others felt that the law did not go far enough. In a crystalline example of the inhospitality tradition, in 1989 (effective January 1, 1992), a law was enacted prohibiting physicians from referring Medicare patients for the provision of clinical laboratory services to entities with which they had a financial relationship, unless the relationship met one of a number of exceptions. Introduced as the "Ethics in Patient Referral Act," that law became known as "Stark I" after its sponsor. The statutory version became an issue because he subsequently introduced a major extension of the types of restriction which had initially applied only to clinical laboratory services. The second iteration of Stark became known as "Stark II," and extended the services implicated by the anti-referral provisions to a range of other "designated health services" including physical therapy, occupational therapy, outpatient drugs, radiation therapy, imaging services including MRI, CT and ultrasound, durable medical equipment, home health services and all inpatient and outpatient hospital services.

Under the Stark II law,⁵ effective January 1, 1995, it is prohibited for a physician (or an immediate family member) to refer a Medicare or Medicaid patient for any designated health service to an entity with which the physician or family member has a financial relationship, unless the relationship meets one of seventeen statutory exceptions. “Physicians” include podiatrists, optometrists, chiropractors (for whom Medicare otherwise recognizes exactly one service for payment) and dentists. It is prohibited to refer and the entity receiving the tainted referral is prohibited from submitting a claim. The statute defines a referral; and it is not the direction of a patient to a source of business. Rather it is the mere ordering of a service, item or good, payable by Medicare—actually the statute says Part B, but this is what happens with midnight drafting and is not to be taken seriously—and the establishment of a treatment plan under which such a designated health service is to be provided.

Remarkably, then, a referral can entail no intentional orientation of the patient to the entity where the financial relationship exists. Violations are punishable by \$15,000 civil money penalty for each improper referral and for each improper claim submission and \$100,000 for a circumvention scheme. Payments made pursuant to a tainted referral are overpayments. There is also potential liability for false claims which are separately punishable by triple the charges and up to \$11,500 per improper claim.

Stark II defines financial relationships to include both direct and indirect compensation relationships. Stark II defines a compensation relationship as any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity The term remuneration includes any remuneration, directly, indirectly, overtly or covertly, in

⁵42 U.S.C.A. §§ 1395nn et seq.

cash or in kind.”⁶ Final regulations under Stark II have only been issued⁷ for part of the statute (“Phase 1”). Not all exceptions have been addressed to date in regulation. This has no effect on whether the statute is violated or not.

The complexity created by the interrelationship between two sets of laws addressing similar issues, in different ways, in totally separate titles of the Social Security Act, not to mention the relatively scarce interpretive guidance (and what there is arrives stunningly late) fosters its own inordinate compliance burdens. Consider that the anti-kickback statute applies to all Medicare, Medicaid and, as of January 1, 1997, federally financed programs, including CHAMPUS, Title V, etc. It applies to whomever is involved in a relevant transaction. Violations can be criminal or civil, and an exclusion may be imposed without a conviction or civil penalty. If you do not conform with a safe harbor, then the situation will be analyzed on a facts and circumstances basis.

Stark II, on the other hand, applies only to physician referrals and then only for the designated services in Medicare and Medicaid and where there is a financial relationship between the referring physician and the referred-to entity. There are two prohibitions under Stark: (1) the prohibition against the referral; and (2) the separate prohibition against a claim submitted pursuant to an improper referral. Stark does not offer safety zones. You either comply or you do not. For these reasons, transactions are usually analyzed first under Stark and then under the anti-kickback statute.

The anti-kickback statute has evolved over twenty-five years with increasingly broader and deeper application. The Stark statute was introduced in 1989 based on then contemporaneous data about physician referrals to joint venture imaging centers in Florida. Both statutes were designed primarily for settings in which fee for service payment was dominant and

⁶42 U.S.C.A. § 1395nn(h)(1)(A), (B).

⁷66 Fed. Reg. 855 (Jan. 4, 2001).

volumes of patients would increase revenue to the billing entity. The continuing vitality of such concern is questionable in a more managed environment and particularly within managed care arrangements where over-utilization is not the real risk; under-use is.⁸

Although there is no question that over-utilization to maximize income is a quality issue, the complexity of these statutes goes well beyond that evil and views any economic benefit to physicians coincident with patient referral as potentially improper. In many instances, the exact same actions in clinical terms when exercised in a managed care setting would be ignored. This disjuncture demonstrates that these laws have little to do with quality. They barely focus on cost. They trigger intense organizational and structural analyses and restructuring based on where economic benefit exists in relationship to patient referral. They distract enormous energies in healthcare from its real problems and they miss the real point.⁹

The legitimate question to be answered in the

⁸The discount safe harbor regulations, managed care safe harbors and shared risk safe harbors are intended to control for issues associated with managed care discounting and other financial practices of providers in exchange for increased and channeled managed care business, but they have little relevance to the quality issues here.

⁹If the concern is whether Medicare pays too much for a service, fee schedules were created to establish in explicit terms the dollar value the public programs are willing to place on certain services. If providers find a way to deliver services within those boundaries so as to make more money and can do so without compromising patient quality, where is the problem? It appears that there is sub rosa, a “most favored nations” philosophy at work here: if any customer can get the service at a lower price, the Medicare program should get that benefit, too. There is, however, no such explicit statutory or regulatory provision in Medicare, although there is a provision which was adopted back in the pre-fee schedule, usual customary and reasonable era of Medicare physician payment, which states that a provider can be excluded from Medicare for charging the program substantially in excess of his usual fees (42 U.S.C.A. § 1320a-7(b)(6)). There is no specified methodology for determining those fees but the continued exist-

physician's referral for any service is whether the provider rendering the service meets quality thresholds and whether that specific patient needs that specific service on that specific day. Someone will make money from the referral service in any event. As long as the quality predicates are present, why does it matter who that is? These statutes are completely incapable of addressing the fundamental issue which can be solved through the application of CPGs.

§ 13:8 —Physician Incentive Plan Regulations

The only purportedly directly quality-relevant piece of this Byzantine regulatory scheme can be found in the physician incentive plan regulations. These are an attempt to define for two pieces of law: (1) the Stark statute and (2) the separate statutory provision which prohibits hospitals and prepaid health care organizations from knowingly making incentive payments to a physician (and prohibits physicians from accepting such payments) as an inducement to reduce or limit services to Medicare beneficiaries or Medicaid recipients, all under the same statutory provision. The physician incentive plan statutory provisions were so contentious that from 1986 through 1990 they were enacted, repealed, and reinserted and then in 1993, as part of the Stark II law were reintroduced as part of the physician compensation exceptions.¹ Thereafter, the Medicare+Choice program was enacted, taking the place of the prepaid health plans that had been part of the original concerns around managed care payments to physicians. Congress then amended the Medicare+Choice provisions to allow physician incen-

tence of this provision raises at least questions if not eyebrows in an era of widespread managed care discounts. Again, however, the quality issues get lost in these cost control provisions.

[Section 13:8]

¹42 U.S.C.A. § 1395nn(e)(3)(B).

tive plans that do not restrict medically necessary care.² If your map through this thicket now seems like something out of Lord of the Rings, we are not yet done. Regulations interpreting the delayed provision (which stemmed from 1986) were originally published in 1996³ and then were amended and revised in a new publication at the end of the same year.⁴ When new regulations under Medicare+Choice were published in June 1998, they announced an intention to adopt what had been published in 1996 with some changes.⁵ Then, further regulations were published in June, 2000, making minor clarifications.⁶

Unlike the safe harbor regulations which define only what is safe, so anything not explicitly safe is analyzed on a facts and circumstances basis, these regulations contain mandates. They confront circumstances where Medicare managed care plans put individual physicians and their “downstream” organizations at financial risk for more than their direct services to patients. The goal is to prohibit any specific payment of any kind, directly or indirectly, under an incentive plan, to a physician or physician group as an inducement to reduce or limit covered medically necessary services furnished under the managed care plan’s contract furnished to an individual enrollee.⁷ The basic intent is unassailable, but as we consider the regulatory approach, keep in mind that two years after their publication we still have almost no data about the actual impact of specific forms of physician incentives in either economic or clinical terms. Still further, two years post-publication, economists tell us:

The complexity of physician behavior, the emergence of

²42 U.S.C.A. § 1395w-22(j)(4).

³61 Fed. Reg. 13,431 (Mar. 27, 1996).

⁴61 Fed. Reg. 69,034 (Dec. 31, 1996).

⁵63 Fed. Reg. 34,968 (June 26, 1998).

⁶65 Fed. Reg. 40,170 (June 29, 2000).

⁷42 C.F.R. § 417.479(d) (2002); 42 C.F.R. §§ 422.208, 422.210 (2002).

payment methods that blend fee for service and capitation, the interdependence of price mechanisms with nonprice mechanisms, the salience of organization as a support for compensation systems, and the remarkable variety and continual change in all arenas suggest that public policymakers should adopt a stance of intellectual humility and a tone of cautious optimism.⁸

Neither is evident in the physician incentive plan regulations, which, in all fairness, were required by Congressional prescription.

The primary technique to safeguard enrollees was to define in what circumstances physicians were placed at “substantial financial risk” by a Medicare health plan for services more than their own. “Substantial financial risk” was the topic garnering the most comments on the March 1996 publication. Where the patient risk pool is less than 25,000 the plan must calculate the swing from lowest to highest potential amounts for which the physicians are at risk. If the result represents 25% of the physician group’s possible compensation then there is substantial financial risk. Bonuses, withholds, capitation, combinations of them or any other form of incentive must be taken into account. Astonishingly, given the pace of health care change, the analysis on which even the 2000 regulations were based relied on data in a 1990 study, which by definition has to reflect an even earlier time. Where such financial risk exists, the protections are (1) required disclosure of how the plan incentivizes its physicians, both to the government and upon request to beneficiaries; and (2) stop-loss coverage and beneficiary surveys if such risk is present. Where the risk devolves to intermediate entities, they become part of the reporting chain. On the other hand, for all its breadth of application on the risk continuum, there is nothing in these regulations that prohibits any transactions or sets parameters for risk assumption in any way. These are purely reporting and

⁸Robinson, “Theory and Practice in The Design of Physician Payment Incentives,” 79 *The Milbank Quarterly* 174 (2001).

informational requirements combined with a stop-loss insurance mandate.

In considering their effect, in 1996 one commenter on the regulations noted that quality and service bonuses seemed not to be the type of risk the regulators were concerned about. The commenter argued that bonuses for high quality, full service capacity, long office hours, accepting all new patients and cost-effectiveness represented no downside risk.⁹ The regulators' response:

While we are supportive of a quality bonus payment, there is very limited experience with its use, and whether a physician will actually receive it is speculative. We will revisit the issue when more information is available on the nature, extent and experience with quality bonuses.¹⁰

The one real change in the final regulations is that the regulators woke up to allow that "Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk."¹¹

As a practical matter the disclosures often require individual physicians to fill out forms they then send to their organizational entities which then send them to the plans. The disclosures purportedly were to be used by the government "to monitor compliance, evaluate the impact of the regulation, and ensure the delivery of high quality care."¹² In the overall maelstrom regarding physician financial incentives, it should be remembered that states weighed in too, enacting laws to address

⁹61 Fed. Reg. 69,041 (Dec. 31, 1996).

¹⁰61 Fed. Reg. 69,041 (Dec. 31, 1996).

¹¹42 C.F.R. § 422.208 (2002) in the definition of "potential payments."

¹²61 Fed. Reg. 69,037 (Dec. 31, 1996).

physician incentives,¹³ thereby simply accreting more and more layers of administrative burden on all the players. In considering the value of all this administrative weight, it should be noted as well that the OIG has targeted physician payment incentives in Medicare managed care in its Work Plan in every year from 1996 to 2001. Medicare managed care is reviewed by PROs.¹⁴ There are still separate and complex quality programs imposed in Medicare + Choice. It would be hard not to wonder if there isn't a real issue of regulatory overkill here, for something about which we do not even have data defining the problem.¹⁵

Now consider our hypothetical market. Case rates based on CPGs, defined fee for service payment within a range as determined by a CPG—these do not entail financial risk under the regulatory definition. Payment is predetermined and reflects the clinical needs of the patient. Variability turns only on the patient's condition, which, in a well designed system would incorporate "case breakers" or co-morbid conditions that shift the care outside the defined CPG, thereby triggering an alternative payment methodology. The easiest default in that instance would be straight CPT based fee for service payment. How relatively simple by comparison with all of these questions about financial incentives! The proposed approach gives to physicians medical management risk while retaining to the insurance

¹³See Anderlik, "Efforts to Regulate Physician Financial Incentives," (Jan. 20, 1999), <http://www.law.uh.edu/healthlaw/perspectives/Managed/990120Efforts.html>.

¹⁴42 U.S.C.A. § 1320c(3)(a)(4)(B). Medicare + Choice has its own quality managed and reporting requirements in the QIMSC (Quality Improvement System for Managed Care) and QAP1 (Quality Assessment and Performance Improvement) provisions of the regulations and operational policy letters. <http://www.hcfa.gov/medicare/mgdqual.htm>.

¹⁵For a discussion of the essentially unmanageably complex regulatory context for Medicare + Choice, see Krasner, "Medicare + Choice: Swamped by Regulation," *Health Law Handbook* 479-500 (Gosfield, ed. 2000).

entity, actuarial or incident risk, for which the insurer is licensed but the physician group is not. Still, the physician incentive plan rules apply to Medicare and Medicaid managed care entities which receive payments from the government and then manage financial risk based on that government compensation. Another related technique to motivate physician behavior was briefly far more popular at the hospital-physician level and even without formal regulations garnered another less than hospitable government response.

§ 13:9 —Gainsharing

Like much in healthcare, the concept of gainsharing had a long history before its application by hospitals in relationships with physicians. Beginning in the 1930s as a form of compensation referred to as the Scanlon Plan, through a variety of other iterations, techniques to motivate workers by giving them a share in the success of the enterprise have been present up to and into the current era, primarily, however, in manufacturing industries:

Simply put, gainsharing is a group bonus plan—as opposed to more traditional individual plans—designed to encourage workers to surpass previous company performance standards such as productivity, quality, or any other objectives corporate management can adequately measure. When the program is effective, the extra profits or savings are paid out in cash above and beyond salary. Generally, the workforce receives about half of the gains and the company garnishes an equal share.¹

Where gain sharing has been successful it has been implemented as part of overall team involvement, with realistic expectations among the workers, and careful communication of the goals and measures selected.

[Section 13:9]

¹Taylor, “Gainsharing the Wealth More Companies Turn to an Old-Fashioned Incentive,” Reengineering Resource Center (Aug. 1996), <http://www.reengineering.com/articles/aug96/gainsharing.htm>.

“Gainsharing is really designed to support a culture of high involvement, teamwork and empowerment, and it doesn’t work as well in other kinds of environments.”²

Medicare DRG payments to hospitals are intended to pressure them to manage their own costs; yet the physician “workers” on whom part of their productivity depends are paid in a way which incentivizes them in the opposite direction. It is not surprising, then, that gainsharing would surface as a physician motivation technique, especially in settings where dominant physician groups are responsible for large portions of hospital expenses based on their ordering, prescribing and treatment regimens. Hospitals do not practice medicine and cannot provide any of their services without a physician order to do so. Physician behavior, then, can have direct and major impacts on hospital revenues which is why we have so much rhetoric about aligning incentives in the hospital sector long after that chant has faded from managed care.³

Against this background, and heavily marketed by consulting firms, hospital-physician gainsharing focused most often on specific high cost DRGs, often cardiac in nature. Hospitals proposed to enter into financial arrangements of various types with their physicians to reward them for helping to cut hospital costs. Whether these programs were effective aside, the Inspector General was not positively impressed.

²Taylor, “Gainsharing the Wealth More Companies Turn to an Old-Fashioned Incentive,” Reengineering Resource Center (Aug. 1996), <http://www.reengineering.com/articles/aug96/gainsharing.htm>. The law at issue for our consideration is the 1986 provision which originally included prepaid health plans in the incentive plan prohibitions.

³Some who are serious worshippers at the shrine of economic suspicion might argue far more strongly for checks and balances model with intentionally diverging incentives. Whichever orthodoxy one follows though, it is fair to say neither model is purely present in today’s world.

In a “Special Advisory Bulletin,”⁴ the OIG characterized the law on payments to physicians to reduce or limit services to beneficiaries as follows:

The statutory proscription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute.⁵

This is not mere inhospitality. This is battening down the hatches and heading for the air-raid shelter. Still further, reduction alone does not account for the fact that we now know that much of poor quality in health care involves over-utilization or mis-utilization.⁶ Reducing and limiting inappropriate services, in fact, is often the pro-quality policy. The OIG attempts to acknowledge that some good might result from gainsharing.

The OIG recognizes that hospitals have a legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs. Savings that do not affect the quality of patient care may be generated in many ways including substituting lower cost but equally effective medical supplies, item or devices; re-engineering hospital surgical and medical procedures; reducing utilization of medically unnecessary ancillary services; and reducing

⁴Office of the Inspector General, “Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries,” (July 1999), <http://oig.hhs.gov/frdalrt/gainsh.htm>.

⁵Office of the Inspector General, “Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries,” (July 1999), <http://oig.hhs.gov/frdalrt/gainsh.htm>.

⁶Chassin, Galvin, et al., “The Urgent Need to Improve Health Care Quality,” 280 JAMA 1000 (Sept. 16, 1998), and Corrigan, et al., National Academy Press (Washington, D.C. 2001).

unnecessary lengths of stay. Achieving these savings may require substantial effort on the part of the participating physicians. Obviously, a reduction in health care costs that does not adversely affect the quality of the health care provided to patients is in the best interest of the nation's health care system. Nonetheless, the plain language of section 1128A(b)(1) of the Act prohibits tying the physicians' compensation for such services to reductions or limitations in items or services provided to patients under the physicians' clinical care.⁷

So, for physicians to expend what the OIG acknowledges would be "substantial effort" to assist their hospital partners to cut costs cannot be recognized economically if there is a reduction in services merely coincident with the payment. It is difficult to know what "tying" of compensation entails. Earlier in the Bulletin, the OIG says that the reduction itself need not even occur, it is the mere encouragement of reduction which is at issue. Citing a high risk of abuse and the difficulty in determining if there were adequate and accurate measures of quality of care that would provide assurance that there is no adverse impact on patient care, the OIG refused to issue a safe harbor to address gainsharing, and indicated it would not even issue Advisory Opinions on the practice. The effect went beyond chilling to glacial. Most gainsharing programs were abandoned immediately.

It was with some surprise, then, that eighteen months later the industry read an OIG Advisory Opinion⁸ not only precisely on point, but far more positive in its views. Unlike many of the gainsharing proposals which had been circulating at the time of the Special Bulletin, here a group of cardiac surgeons would be paid 50% of the first year cost savings appreciated by the hospital as a result of the surgeons using specific

⁷Office of the Inspector General, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999).

⁸OIG Advisory Opinion No. 01-1 (Jan. 11, 2001).

surgical supplies only as needed, agreeing to the substitution of less costly items and supplies in the specified surgical procedures and limiting the use of a pre-operative medication to prevent hemorrhaging. It is noteworthy that the physicians were not exclusively contracted to the hospital, but accounted for more than 85% of the cardiac surgical procedures performed in the facility. The compensation program was not even made available to other physicians with privileges to perform the same procedures.

Savings were to be measured against a historical base and reductions below the floors for the then current usage rates would not be included in the compensation to the surgeons. The recommendations from outside consultants as to how to reduce costs, on specific DRGs for specific procedures, constituted 19 separate measurable actions. Cost savings at the end of the year would be calculated for each recommendation separately.

A number of other safeguards were present in the proposal. No payment would be made for cost savings generated by increases in the numbers of procedures, so that increased referrals would not increase the compensation to the physicians. The payment program would be managed and data maintained by an outside Program Administrator. If the data showed that more costly patients were steered to other facilities during the year, the physician(s) making such referral decisions would be terminated from the program. The surgeons and the hospital would disclose the arrangement to patients prior to admission and if the decision to operate was made after admission, prior to patient consent.

The OIG indicated its concern with four aspects of gainsharing generally: "(i) stinting on patient care; (ii) 'cherry picking' healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a 'race to the bottom') among hospitals offering cost sharing programs to foster physician loyalty and to attract more

referrals.”⁹ The OIG analyzed the arrangement under the hospital-physician incentive civil money penalty law and under the anti-kickback statute, ignoring the Stark law as outside its purview.

Addressing the civil money penalty issue the OIG acknowledged that reduction of care is sometimes appropriate but said “whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.”¹⁰ Reduction in *improper* services would violate the statute too, according to this analysis, in any instance in which the reduction was given economic recognition in payment to the physicians. Surprisingly, then, announcing that they would *not* take action against the participants, the OIG distinguished the safeguards in this narrow and well defined program from the tenets of most gainsharing they had seen which lacked verifiable measures, did not link individual action to specific payment amounts, did not have any mechanisms to take into account other factors besides the physician actions as having produced the savings, and, among other things, claimed quality indicators which were of questionable validity and statistical significance.

The tandem piece was the anti-kickback analysis where the OIG looked to the personal services and management services safe harbors. The touchstone of both of these, is, of course, fair market value, allowing payments that do not reflect the volume or value of referrals. Although the payment of 50% of savings does not meet the safety factor of aggregate compensation stated in advance, the baseline measure against historical data acted as a cap on the amount the physicians would get. The formula also specifically excluded increased referrals as contributors to the cost savings. Taken together the OIG found a way to position its analysis as consistent with its prior sweeping hostility. Given that the Stark statute also has a personal ser-

⁹OIG Advisory Opinion No. 01-1, 6 (Jan. 11, 2001).

¹⁰OIG Advisory Opinion No. 01-1, 8 (Jan. 11, 2001).

vices exception, and that fair market value is also the gravamen of its protections, it is unlikely that a gainsharing program found to meet OIG requirements would be seen to violate the Stark statute on these points.

Still, in the overall analysis of gainsharing and hospital-physician collaboration, it is interesting that the requestor of the Advisory Opinion asserted—albeit in the form of a “certification”—that “this payment methodology will generate payments to the Surgeon Group that will be consistent with fair market value for services rendered to the hospital in arms-length transactions.”¹¹ The OIG does not dwell on, but must have accepted this assertion, since there can be no safety in something that does not reflect fair market value, although the OIG generally refuses to opine on the subject because it is statutorily precluded from doing so. Here it stepped out to say “While we are precluded from opining on whether a payment is fair market value, the payments under the Proposed Arrangement do not appear unreasonable, given among other things, the nature of the nineteen recommended actions, the specificity of the payment formula and the cap on total remuneration to the Surgeon Group.”¹² Reasonableness is not, despite the OIG’s good intentions, synonymous with fair market value, at least according to their own regulations, which merely state that fair market value is that which pertains “in arms-length transactions.” Where does this lead us? To a far better land than the one we have traversed.

§ 13:10 —Possibilities Explored

The physician incentive plan regulations pose more of an administrative burden than an operational one, since they neither prohibit nor mandate any form of incentive. Payment based on clinical guidelines cannot

¹¹OIG Advisory Opinion No. 01-1, 6 (Jan. 11, 2001).

¹²OIG Advisory Opinion No. 01-1, 13 (Jan. 11, 2001).

be seen as falling within the “substantial financial risk” definition of those regulations. Good news for our hypothetical market.

In contrast, the views of the OIG on hospital-physician financial alignments is not a welcoming one. Still, two relevant and positive conclusions can be drawn—one directly on point, and one positive in its implications: (1) When properly designed, narrowly focused, and fixed in amount, duration and scope, financial relationships between hospitals and physicians that are intended to improve the quality-safety environment can be crafted to effectively navigate the hills and valleys of these still barely charted terrains; and (2) There is no evidence cited or yet available on a broad basis that paying the physicians a part of the hospital’s savings for doing the hospital’s work is either effective or is a sustainable business model for this critical relationship. Once the initial savings accrue, if they do, how much more cutting can the physicians generate? Since the compensation for their economic value comes out of lowered expenses and the least expensive resources are none at all, there is a very finite boundary to the longevity of these arrangements. This may reassure the OIG but it does not create a decent model for an on-going relationship. If the physicians are not motivated to make these changes without the reward of a piece of the savings, what will make them do it after the initial payment? Why would they not revert to prior behavior? Moreover, while physicians are responding to that incentive, what are they doing about their more basic challenges in terms of solidifying their doctor-patient relationships by, for example, increasing their time with those patients, lowering expenses in the practice so less empathetic patient throughput is not where they end up? Still further, it is hard to imagine that disclosing to the patient the type of financial relationship in the proposed arrangement will strengthen the bonds of trust between doctor and patient.

How can the payment in a model like the proposed arrangement be considered fair market value? This

could only be the case if other consultants who do not refer patients and have the ability to affect the actual implementation of programs (and one would ask how that could happen?) charge and are paid on the same basis. This is also speculative at best. How can all of this be positive? Taken together, the best message may be that gainsharing as a business model between hospitals and physicians does not merit anywhere near the attention it has garnered to date, thereby liberating both parties to focus on what each does best.

As to how they can work more effectively together, let us consider the many activities within a hospital around which physician input is critical to define, create and sustain a clinical culture of quality.¹ The long tradition of organized medical staffs has had as its core responsibility, delegated from the hospital board to the physicians, the selection of the pool of physicians who would jointly utilize the facilities of the institution (privileging, credentialing, quality monitoring of the physicians). This same tradition has depended on the volunteer spirit of the staff members to contribute considerable time and energy in the exercise of this function. Although viewed as heresy in some physician quarters, some hospital advocates have long held that this activity should be assigned to paid consultants or employees.² The economic value of these judgments to the hospital in terms of risk management and quality performance is obvious. There is no reason physicians cannot be paid for these activities on a fair market value basis. Such an approach would assure that many of the failures of

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¹For a consideration of why the role of physicians is so important in hospitals and a consideration of the specific values physicians bring to bear in what they do and where hospitals ought seek to bring them to the table as true collaborators, see Gosfield, *Quality and Clinical Culture: The Critical Role of Physicians in Accountable Healthcare Organizations*, American Medical Association (1998), <http://www.ama-assn.org/ama/pub/article/371-477.html>.

²Horty, *ActionKit for Hospital Law* (Mar. 1989).

physicians to exercise these roles effectively³ (inconsistent attendance at meetings, failure to evaluate data completely, giving short shrift to difficult judgments because of time pressures, among others) would be remedied.

In our hypothetical community, the most critical driver within the hospital and throughout the context is CPGs. The model will not work if the evidence based foundations for it—the CPGS—are not selected carefully and wholeheartedly endorsed by the physicians who will live by them for their own direct payment, and for most other activities in which they engage. Consequently, to select, implement, monitor and safeguard as timely and valid the CPGs at work in the system are fundamental activities for which physicians can be paid fair market value on an on-going basis. Analysis of the data which emerges from tracking conformity to guidelines or deviation from them and its implications for improved care also must involve the physicians. Related activities pertaining to elimination of clinical mistakes by the physicians as part of the care team cannot be conducted without physician involvement. Financial and non-financial incentives to be used within the facility or system to sustain physician engagement cannot work without physician input in their establishment and operation. All of these activities can be seen as fairly consistent with, although something of an expansion in, traditional medical staff roles.

A broader view of the value of physicians to the model would take into account a variety of hospital related functions in which physicians, historically, have been less involved. Payor contract negotiations where the issue is whether the payor's rate can support the quality at issue in the applicable CPGs is rarely an activity to

³See Gosfield, *Quality and Clinical Culture: The Critical Role of Physicians in Accountable Healthcare Organizations*, American Medical Association (1998), <http://www.ama-assn.org/ama/pub/article/371-477.html>, for a discussion of the ways in which physicians undermine their own effectiveness as collaborators.

which physician leadership has been invited. Most hospital financial officers believe that physicians cannot understand the financial issues at work in these contracts. As a result, not surprisingly, physicians often distrust the resulting payment arrangements that the facility administration negotiates, even where the physician's own payment is not on the table. Still further they often believe, and usually are right, that the hospital's finance driven negotiators have little understanding of the fundamental clinical issues these payment terms create. Basing these negotiations on CPGs can highlight in far more obvious terms where the payor's proposed rate will compromise quality.⁴ Finally, where CPGs drive payment, negotiations can turn on the clinical implications of payment, which, as we have seen, is virtually impossible in traditional payment models, whether fee for service, capitation, or its hospital equivalent—DRGs—which are based on historical utilization of resources and not patient clinical needs.

One of the most fundamental challenges for everyone in health care today is how to maximize the use of information systems without creating undue administrative burden. Physicians are rarely included in the discussions within hospitals about the choice of their systems until the selection and capital investment have already been made. Typically, the hospital has had different information technologies for different activities (billing and collection, medical records, financial reporting) and none of them has taken into account their clinical implications nor whether the reports they generate can be understood or used by the physicians whom the facility would seek to engage. In our hypothetical scenario, the information systems and their use are critical to the operation of the model. The involvement of

⁴The success of such an approach, however, depends on a solid understanding of what it costs to treat a patient for a condition. This understanding has to start from a basic statement of what the patient needs to have done by definition a CPG.

the physicians in the selection and design of these mechanisms is, therefore, essential if the model is to work effectively and not smack of a cram down approach which is neither useful nor trustworthy as far as the physicians are concerned. Their involvement here can also be recognized with fair market value payments for their input.

Three other basic functions in our model sustain its clinical consistency: strategic planning (what is the business of the system and the brand we seek to project); budgeting (do we have the appropriate resources in place to make our strategic plan happen) and manpower planning (do we have the appropriate constellation of personnel to fulfill these goals). Most hospitals have typically not only not involved physicians in these processes, they have not taken into account in these critical management issues the clinical mandates that our posited scenario entails. Unless these activities are built on a bedrock of evidence based clinical purpose, the resulting system will simply replicate the failures identified in *Crossing the Quality Chasm*. To make quality happen, a different approach to these basic business judgments will be necessary. The more consistent they are with quality needs the more the entire approach inherently makes the business case for quality at all levels of the enterprise.

This discussion has unfolded in the context of the implications of the anti-kickback and anti-referral laws which are fundamentally about financial relationships. At the same time, cost pressures in the system have increased; so, where will the money come from to pay the physicians for the economic value they bring to the hospital in its quality-driven efforts? Facilities and systems adopting these principles will, obviously, have to make judgments regarding which of these functions merit payment. But, it can be expected that where the operational principles coincide for the physicians and the facility—where the same CPGs are used in the office, in the hospital, and in relationship to payors—where consistency is present throughout, physicians

will see their own self interest in fostering a setting where there is less administrative burden on them and a greater opportunity to do the right thing for their patients. Where they have the ability to maximize their own efficiencies by using a consistent logic, their long tradition of volunteerism can be called on to sustain their interactions with the hospital. The ultimate balance between fair market value recognition of physician economic value as quality collaborators and volunteerism to make a better clinical culture can only be defined within the specific setting where such a system is adopted. Along the way yet another complex regulatory landscape awaits.

§ 13:11 HIPAA

Perhaps the most daunting, time consuming to understand, complicated, labor and systems intensive regulations to hit health care in the last thirty years are those published under HIPAA—not under the fraud and abuse provisions which were hair raising themselves, but under the oxymoronically named “administrative simplification” provisions.¹ The initial intent had been to simplify claims processing by creating uniform standards for electronic claims reporting. There was significant concern for the security of these mechanisms.² There was also attention paid to patient confidentiality and privacy so, in a bizarre reverse default provision, the statute provided that if Congress failed to enact privacy standards within three years of the law’s enactment, the Secretary of HHS was directed to do so. The privacy standards were contemplated as only one piece of a complex set of requirements for a

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¹Part C, Title XI, Social Security Act; 45 U.S.C.A. §§ 1320d et seq.

²For a brief discussion of legal authorities dealing only with security measures, which will not be discussed further here, see Shay, “A Survey of Security in Electronic Health Information,” *Health Law Handbook* 27-53 (Gosfield, ed. 2001).

more electronic, uniform, claims submission system in health care. These components included transactions and data elements, unique health identifiers, security standards, electronic signatures, code sets and transfer of information among health plans. The focus was on health plans and electronic interchange of data.

Despite considerable efforts to stimulate congressional action, Congress defaulted. So, in a parting shot at the end of the troubled Clinton Administration, some four years after the law's enactment, privacy standards were published on December 28, 2000.³ The preface alone is 336 pages in the *Federal Register* to explain 31 pages of regulations. This is no Dionysian rhapsody. This is a hyper-manic Bacchanalian frenzy. The actual contents of the regulations are far worse if we are seeking the smooth interchange of data among critical quality collaborators who must be engaged to facilitate quality, not only in the aspirational terms of *Crossing the Quality Chasm*, but in today's vineyards of quality improvement. In these regulations, truly, anything that is not mandatory is prohibited and what is mandatory is considerable. The hue and cry which resulted is so well known that it is not necessary to catalogue or cite it here, although by DHHS's own count they received more than 11,000 letters and comments on the *final* regulations, let alone the proposed ones.

By July, 2001, the Office of Civil Rights in DHHS⁴ sought to quell the turmoil with an easily digestible listing of Frequently Asked Questions (FAQs) posted on

³61 Fed. Reg. 82,462 (Dec. 28, 2000).

⁴That OCR has administrative responsibility for the law says something significant about how rules intended to facilitate health care system data interchange became rules on patients' rights. The mission of the Office in its own words follows: "The Department of Health and Human Services, through the Office for Civil Rights, promotes and ensures that people have equal access to and opportunity to participate in and receive services in all HHS programs without facing unlawful discrimination. Through prevention and elimination of unlawful discrimination, the Office for Civil Rights helps HHS carry out its overall mission of improving the

their website in the form of Guidance.⁵ These simplifications themselves print to 51 pages in length. Acknowledging the regulatory philosophy set forth in this document is critical to understand how the privacy regulations will affect quality for those who fall within its domain: health plans, health care clearinghouses, and providers which transmit protected health information electronically.⁶ The compliance date is April 14, 2003.

§ 13:12 —Basic Regulatory Philosophy and Contents

That there is a need for confidentiality and privacy of personal health care information is not in question. The medical record spawns interchange and commerce in health care information:

Insurers freely romp through it. Fragments zoom from agency to agency. Computer files are hacked, faxes are sent to the wrong number, messages are left on the wrong machine, wastepaper flies through the streets—entropy scatters confidential medical data everywhere. Malice and happenstance can also play a role: your neighbor's husband lands a clerical hospital job—as actually happened to one of my patients—and next thing

health and well-being of all people affected by its many programs.”
<http://www.hhs.gov/ocr/mission.html>.

⁵OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

⁶Because of the profound complexity in the regulatory scheme and the fact that this consideration is limited to a basic understanding of regulatory philosophy and how it runs at cross purposes with quality, references in this discussion will be made to the greatest extent possible to the Guidance. Where the guidance does not address an issue, the citation will be to the regulation itself.

you know the intimate details of your venereal diseases are all over town.¹

These regulations are designed to prevent and punish these occurrences.

The basic philosophy of the regulations is that patient consent must be obtained for the use and disclosure of personal health information (“PHI”) to be used in treatment, payment or healthcare operations (“TPO”). Very strong patient control over health care data both maintained and disseminated about them is a hallmark of these rules. The regulations apply only to “covered entities”—health care providers that transmit PHI electronically, plans and health care clearinghouses. The rules are not the same for all players. Special burdens are imposed on providers. For them to conduct the basic functions of TPO even if they do not share the information with any other party, a patient consent must be obtained. The only exception among health care providers is those who have an indirect treatment relationship with the patient, such as a pathologist and in some instances a radiologist. Although the consent need be obtained only once, it can be revoked and restricted by the patient. The covered entity (physician, hospital, other provider) may refuse the patient treatment and need not accede to the restriction but is bound by any restriction to which it agrees. Health plans and data clearinghouses do not need consent to use PHI in TPO.



The consent burden is individual; and the consent obtained by one covered entity may not be relied upon by another. The absurdity of this requirement is such that OCR admits that a pharmacist cannot use basic information about a patient when a physician calls in a prescription, unless the patient has provided a written consent to the pharmacist; nor may a specialist or

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¹Zuger, “On Record: Conflicting Obligations,” *New York Times* F5 (Jan. 1, 2002).

hospital to whom the patient is presenting for the first time use PHI to set up appointments or schedule procedures!² Although there is an exception for emergency situations, there is no definition of these and the health care provider “must exercise their professional judgment to determine whether obtaining consent would interfere with the timely delivery of necessary health care.”³ The Secretary states that DHHS intends to propose modifications to these aspects of the rule.

Consent, however, is only the first part of the patient control features. For any use or disclosure which is not within the definitions of TPO an “authorization” must be obtained. Unlike consents, all covered entities must obtain “authorizations” for uses which are not for TPO. An authorization is a customized document which states the proposed uses and disclosures of the PHI; it has an expiration date. There are even stricter standards for certain categories of data. A provider would need to obtain an authorization (the longer, more onerous form of patient approval) to disclose PHI maintained in psychotherapy notes.

The third administrative component of the informational aspects of these rules is the requirement that entities provide patients with “Notice” of their TPO uses of data so the consent is meaningful.⁴ How meaningful is a question since, although the Notice must state how the provider uses PHI, the rules do not

²OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 9 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

³OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 10 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

⁴45 C.F.R. § 164.520 (2002).

require that the individual read the Notice nor that the covered entity explain each item in the Notice.⁵

The Notice is similar to those required of financial organizations but goes further. The Notice must describe and include at least one example of the types of uses and disclosures the covered entity is permitted to make for each of the elements of TPO. Other specific language must be included; and the Notice must also include a description of each of the other purposes for which the entity is permitted or required to use or disclose PHI without consent or authorization. Although a mere list of the categories noted in the regulations can be crafted without real difficulty, it is doubtful the regulators themselves could state all the implied applications of data under the permitted uses. Still further for each of fund-raising, appointment reminders, or a group health plan disclosure to the sponsor of the plan, a separate specific statement must be included. Six enumerated patient's rights must be set forth. Reportedly the American Hospital Association drafted a model Notice which was twelve pages in length!

Where disclosure of PHI will be made and is permitted, the rule imposes boundaries on what may be disclosed, even after consent has been obtained. The disclosure must be limited to the "minimum necessary" PHI to accomplish the purpose. This limit does not pertain to disclosures to or requests by a health care provider for treatment purposes, pursuant to an authorization when it is requested by the individual, uses or disclosures required for compliance with the standardized transactions rules, to DHHS for enforcement or as otherwise required by law.

The "minimum necessary" standard has generated profound concern in the healthcare industry. From one end of the implementation spectrum many are concerned over the labor required to determine what data

⁵OCR Guidance, "Statements for Privacy of Individually Identifiable Health Information," TA 164.000.00, 12 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

to select as “the minimum necessary” and whether that judgment will stand up to the heat of scrutiny from enforcers. At the other end is concern as to whether it is ever permitted to turn over a complete medical record. Obviously such a minimum necessary standard cannot incorporate definitions to cover all situations where PHI will be disclosed. “The rule requires covered entities to make their own assessment of what PHI is reasonably necessary for a particular purpose, given the characteristics of their business and workforce, and to implement policies and procedures accordingly.”⁶ The Guidance attempts to emphasize the reasonableness standard which the government expects providers to apply to make this standard real. Although some commenters raised concern over the need to restructure existing workflow systems, including redesign of office space and upgrades of computer systems to meet these standards, the OCR has said such wholesale redesign is not necessary. On the other hand “covered entities may need to make certain adjustments to their facilities to minimize access, such as isolating and locking file cabinets or records rooms, or providing additional security, such as passwords on computers maintaining personal information.”⁷

When the covered entity uses subcontractors to perform TPO, the rule goes further and requires them to inquire of and demand of their “business associates” assurances that they have in place many of the same safeguards. Here the rule graciously at least allows providers and plans to give PHI to business associates without additional consent, but still conditions such disclosures on the provider or plan obtaining through contract ‘satisfactory assurances’ both that the business

⁶OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 17 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

⁷OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 20 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

associate will use the information only for the purposes for which they were engaged by the covered entity and also will impose similar —although as characterized by OCR, far narrower—safeguards. Business associates are defined as third parties to the covered entity, such as billing companies, utilization review entities, or other outside suppliers who perform TPO functions on behalf of the covered entity. These requirements do not pertain to covered entities which disclose PHO to providers for treatment purposes—“for example, information exchanges between a hospital and physicians with admitting privileges at the hospital”⁸ —even if they would otherwise meet the definition of a business associate.

The regulations go further to take on yet another aspect of confidentiality which the statute did not address. Many people today are aware of the horror stories of computer hackers violating privacy through intentional acts and other disclosures of electronic information. Most confidentiality breaches, however, are made through mere human mistake or carelessness. Many observers have known of the longstanding principles of confidentiality in doctor-patient relationships, and that as a practical matter, in hospital settings and physician offices inadvertent disclosure of information occurs, including through conversation in elevators, for example. There is no question that these lapses can be significant to the patient when they occur. No one would argue that all types of providers should work hard to prevent such disclosures and that policies and procedures to maximize confidential handling of data are worthwhile.

This entire regulatory construct, though, has been deliberately and explicitly extended to encompass any communication of individually identifiable PHI in all forms, electronic, written, oral or any other. Remember that the only providers who are covered entities are

⁸OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 27 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

those that transmit PHI in electronic form. So a three physician practice without a computer or fax machine would be exempt from all of these requirements, including the oral communication limitations. Reference to oral communication was not present in the statute, nor in the proposed regulations. It stems from the regulatory philosophy that “If oral communications were not covered, any health information could be disclosed to any person, so long as the disclosure was spoken.”⁹ Covered entities must “reasonably safeguard” PHI from any violation of the rule whether intentional or unintentional.

The implications of this requirement in the real world also have raised alarms. One of the FAQs addressed by OCR is “If health care providers engage in confidential conversations with other providers or with patients, have they violated the rule if there is a possibility they could be overheard?”¹⁰ The OCR “understands that overheard communications are unavoidable,” which is at least some manifestation that they have had moments of being in the here and now. Since those disclosures are not the primary concern in our consideration of how to reorient health care processes and systems within communities to improve quality infrastructures, the instructions and directions in OCR’s observations will not be further elaborated here. But the reader who enjoys both Stephen King novels and Miss Manners’ etiquette books will enjoy both the tone and contents of this government guidance.

The detail in these rules is extraordinary even in the paragons of regulatory excess which we have considered so far; and the privacy rules, awe inspiring as they are, are only part of the overall package of issues to make

⁹OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 22 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

¹⁰OCR Guidance, “Statements for Privacy of Individually Identifiable Health Information,” TA 164.000.00, 23 (July 6, 2001), <http://www.hhs.gov/ocr/hipaa/finalmaster.wpd>.

real the implementation of what used to be administrative simplification. The privacy rules, alone, however, hold serious implications for our hypothetical health care market.

§ 13:13 —Quality vs. Privacy

The exchange of information about care is one of the basic tenets of quality improvement in that you can improve only that which you can measure in the first place. Since so much of health care emanates from provider-patient encounters and even more from doctor-patient interactions, the patient's medical record and data which derives from it, naturally creates PHI. The first challenge under these regulations turns on who will be engaged in gathering and reporting data and what patients must consent to with respect to the information. "Health care operations"—the "O" in TPO—is defined to include:

[Q]uality assessment and improvement activities including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purposes of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.¹

Privileging and credentialing; evaluating practitioner and provider performance; conducting or arranging for medical review or auditing including for fraud and abuse compliance; business planning and development including development or improvement of methods of payment or coverage policies are all included in health care operations. In addition, "treatment" includes not only the actual clinical care of the patient hands on, but also the coordination or management of care by a

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¹45 C.F.R. § 164.501 (2002) Definitions.

health care provider “with a third party” in terms of risk assessment and case management as well as the coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual.²

Before your relief so overtakes you that you skip the next section, remember that a provider entity engaged in any of these activities must obtain a patient consent to do so where PHI is involved (as it is in all of these at some point). So the Notice to the patient of any such entity’s privacy policies must include references to these activities. Still further, even in our hypothetical community, some of these functions will be performed by business associates of the relevant players. We do not know how the enforcers will interpret “with a third party,” but, at a minimum it means a third party who likely is a business associate of the provider, even though not technically subordinate to the provider entity as is implied by subcontracts. Each business associate must have a contract which gives to the primary covered entity, the requisite satisfactory assurances.

Patients who receive the Notice may refuse to give consent. Those instances are relatively easily managed, in HIPAA terms at least, since the provider may refuse treatment in such a case. What, however, is the likelihood a provider will refuse to treat a patient who is overwhelmed by the privacy Notice and deems it easier simply to deny consent? The first problem, then, is that patients may restrict the entry of their data into health care operations so a full picture of quality may not exist. Once having entered treatment, however, the patient may also later revoke or restrict the consent. Then, what happens to his data when the covered entity wants to conduct a quality review?

Remember further, that one covered entity may not rely upon another’s consent, even for health care operations. So if a hospital obtains the patient’s consent

²45 C.F.R. § 164.501 (2002) Definitions.

for its quality improvement activities, it may not disclose any PHI contained within its data to the health plan for its activities, unless the hospital is considered the business associate of the plan in performing those functions for itself, or crazier still, the plan is considered the “business associate” of the hospital and, therefore, is performing TPO on behalf of the hospital. This, of course, is exactly backwards from the logic that operates in the real world. And, without direct access to the PHI, how can the plan verify the validity of the data?³

Still further, for quality improvement purposes, what can we assume about the accuracy of the data maintained as PHI, since patients have the right not only to restrict uses of data but also to “amend” the very data in the record?⁴ And how far does an amendment go? What if the amendment nullifies basic facts stated in the record? The circumstances in which this will happen may be small, but consider the real life story of a man who as a transgendered person mandated that all references in the medical record be to “she” and “her” and that no notation be made that he was a biological man, nor, among other things, of the hormones taken over more than twenty years.⁵ As described by “her” treating physician, “Concealing a patient’s travels from one gender to the other would be more than a little white elision, though. It would be a deliberate act of U.S.C.A. action that would spawn many more (like an alibi for why I was inexplicably neglecting this patient’s routine gynecologic care).”⁶ If patients get to pick and choose not only which data may be used in health care operations, but also which data is maintained for treatment purposes, many of the fundamental premises of quality improvement go out the window.

³See discussion of “Organized Health Care Arrangements,” below.

⁴45 C.F.R. § 164.526(a) (2002).

⁵Zuger, “On Record: Conflicting Obligations,” *New York Times* F5 (Jan. 1, 2002).

⁶Zuger, “On Record: Conflicting Obligations,” *New York Times* F5 (Jan. 1, 2002).

At a minimum, any quality improvement has to turn on an assumption that records of services rendered are, in fact, accurate. It is beyond the scope of this article to address the patient's rights and associated administrative appeals these regulations set up between providers and patients,⁷ but the regulatory scheme is so focused on patients' rights that it may well have the effect, in the end, of undermining their most critical right in health care—the right to the best health care possible for them, rendered in a setting which continually strives for improvement. Although the regulators here purport to have struck a balance between privacy and quality, others in the world of quality assurance have drawn the lines differently in ways which place real importance on quality improvement while still safeguarding privacy.⁸ These rules manifest a fundamental values orientation that when in doubt, patient privacy takes precedence over all other system needs.

Of course, some might argue that the regulations only deal with *identifiable* health information and that to avoid the concerns just discussed, the discloser need only “de-identify” the PHI. And so, the regulations have contemplated such an approach, and enunciate the requirements for such de-identification,⁹ which is significantly more easily said than done. De-identified information is information that does not identify an individual and about which there is no reasonable basis to believe the information could be used to identify an

⁷In addition to revocation and refusal of consent, amendment, restriction and access to the data, they also include a right to complain; and they provide appeals rights wherever a right is denied. See King, “HIPAA; Privacy Standards: Driving a Wedge Between Patients and the Health Field,” *Health Law Handbook* 3-26 (Gosfield, ed. 2001). Still further there is an entire compliance piece which is far more prescriptive than the OIG's guidance for fraud and abuse compliance.

⁸See NCQA-JCAHO, *Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment*, <http://www.ncqa.org/docs/reports/confide.doc>.

⁹45 C.F.R. § 164.514 (2002).

individual. This is a different standard from the PRO data disclosure regulation which forbids the release of “confidential information” which is defined, *inter alia*, as data that explicitly or implicitly identifies a patient.¹⁰

The HIPAA privacy regulations recognize that in the new electronic age, fragmented and dissociated information can be reconstructed to identify someone. So, a covered entity may determine that health information is not individually identifiable only if—in the now clarion spirit of inhospitality—nineteen specific forms of identification have been removed with respect not only to the individual himself, but also his relatives, employers or household members! One can only theorize about which degrees of affinity and consanguinity these regulations intend to incorporate in the term “relatives,” nor what standards of residence would pertain to “household members.” Likely the employer could be readily identified and all inappropriate references to it removed.

Fear not though. There is another option. In a more trustful government mode than that otherwise in play here, instead of relying on the checklist, a covered entity can rely on the judgment as to whether the data has been sufficiently de-identified by “a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not identifiable,” that there is very little likelihood the data could identify someone.¹¹ Statisticians everywhere are cheering, no doubt. Still, the risks associated with whether that expert views the data in a way shared by enforcers is completely unknown. Fools rush in where angels are quaking in their seraphic boots. If there has not been a strong business case for quality improvement up until now, to have to de-identify data in order to conduct this activity that is so essential for a strong healthcare system is a virtually insurmountable barrier. Luckily

¹⁰42 C.F.R. § 480.101(b) (2002).

¹¹45 C.F.R. § 164.514(b)(1) (2002).

our fellowship of the ring may find some pathways under this mountain.

§ 13:14 —Joining Forces

There are two fundamental approaches to sharing PHI for collaborative quality initiatives which can serve our hypothetical market: (1) aggregations of covered entities into single entities;¹ and (2) organized health care arrangements. For the former, the defining characteristic is that otherwise legally distinct entities share common ownership and control, such as a chain of hospitals across twenty states.² Under this definition, in our scenario a system of hospitals, nursing homes, and a faculty practice plan within the same community might be able to qualify as an affiliated covered entity and use a single shared notice of privacy practices and a single consent form. Of course, the organizational interrelationships must be documented, and the liabilities which otherwise would pertain to each of the elements still would be in effect.

Of greater significance for our hypothetical market is the “organized health care arrangement” (“OHCA”) defined as:

[C]linical or operational integration among legally separate covered entities in which it is often necessary to share protected health information for the joint management and operations of the arrangement. They may range in legal structure, but a key component of these arrangements is that individuals who obtain services from them have an expectation that these arrangements are integrated and that they jointly manage their operations.”³

The discussion recognizes the need for physicians, nurses, and hospital personnel to interact in common cause for TPO in a hospital setting even when they are

[Section 13:14]

¹45 C.F.R. § 164.504(d) (2002).

²65 Fed. Reg. 82,503 (Dec. 28, 2000).

³65 Fed. Reg. 82,494 (Dec. 28, 2000).

not otherwise legally under one rubric. This is fine as far as it goes, but it is the only example, and an easy shot at that, of what they consider a truly integrated health care setting. One can presume that where non-employed physicians of the medical staff join with the hospital to evaluate care as part of their review of their own care, or as part of gainsharing, or even as part of activities similar to those of a PHO, without actually forming a contracting entity, these could potentially qualify as clinically integrated. Although the preface to the regulations states that “While protected health information may be freely shared among providers for treatment purposes under other provisions of this rule, some of these joint activities also support the health care operations of one or more participants in the joint arrangement.”⁴

The OHCA definition goes on to recognize an “organized system of health care” in which more than one covered entity participates and in which the participating covered entities hold themselves out to the public as participating. Here the joint arrangements must include at least one of the following: (1) utilization review among the covered entities or by a third party for them; (2) quality assessment and improvement activities in which the covered entities evaluate themselves or a third party does it for them; or (3) payment activities where there is shared financial risk and the involved covered entities share data which is reviewed by other covered entities in the arrangement to administer the shared risk.⁵ Such an organizational structure may use a joint notice and joint consent.⁶ Presumably a health plan in relationship to its contracted network of providers together would qualify, but, amazingly, this simple aspect of health care today is not addressed in the relevant discussion.

Unfortunately, the regulations offer little more by

⁴65 Fed. Reg. 82,494 (Dec. 28, 2000).

⁵45 C.F.R. § 164.501 (2002).

⁶45 C.F.R. §§ 164.506(f)(1), 164.520(d) (2002).

way of explanation or application. The best we can find at this point in these prefatory discussions is that communities seeking to work along our model will have to consider structuring relevant components as an organized health care system. However, what qualifies as “holding itself out” to the public as participants for the public’s “having an expectation” that an entity is clinically or operationally integrated or jointly managed is utterly unelucidated in the discussion. This is particularly true where the entity is clinically integrated for operations but not necessarily for treatment.

The major virtue of the prefatory acknowledgement and definitional recognition seems to lie in the fact that the definition of a “business associate” which otherwise would be applicable. That definition requires that the contracted partner is performing a function *on behalf of* the covered entity. In our model, the participants may be co-equal and the functions performed serve sometimes their own needs but, often as part of the joint enterprise, benefit all. They are not acting technically on behalf of any one of them. This definition offers tantalizing but still mysterious possibilities. There is a definition of “data aggregation” which refers to a business associate combining PHI it receives from one entity with PHI received as the business associate of another entity “to permit data analyses that relate to the health care operations of the respective covered entities.”⁷ In a more hospitable environment, quality driven participants might breathe a sigh of relief but the institutionalized inhospitality religion of this program offers little comfort. Data aggregation is not mentioned in the limited provisions on organized health care arrangements and is mired in the restrictions of business associate relationships. Still, with enough contractual assurances throughout the shire, these functions could be performed with everyone functioning as the business associate of everyone else to get the necessary data ag-

⁷45 C.F.R. § 164.501 (2002) Definitions.

gregation to perform real benchmarking and quality improvement.

Our scenario posits freely shared information about clinical quality and patient perceptions of care. It anticipates credentialing and involvement of physicians at the hospital or the healthcare system in a wide variety of activities that would have to fall under the organized health care arrangement if all the players are to have access to the fundamental clinical and other information which emanates from PHI. The whole undertaking is cloaked in clinical integration of care based on CPGs. This integration is also important to another legal morasse.

§ 13:15 Antitrust and Clinical Integration

Emerging from the cobwebs and corners of HIPAA, we now find ourselves confronting another aspect of the law which has stymied both plans and providers, although the predominant concern has come from the provider arena—namely the ways in which the antitrust laws can thwart the equities of provider-payer interactions. In our scenario we have proposed that payment schemes be jointly worked out between payors and providers, but life rarely evolves so neatly. In the real world, to negotiate rates, someone has to step out and put the first number on the table. In the world of antitrust where the inhospitality tradition is one sided—anything which does not support competition is venal, evil and for secret, nefarious purposes—negotiating parties must assess their risks. Whether the risk inherent in any negotiation (will the number be acceptable? did we leave money on the table?) is all that the providers have to fear if they take the laboring oar or whether the Federal Trade Commission and Department of Justice may take an interest, are the choices that will be important to the ability to use the payment principles espoused here to motivate quality-driven behavior.

The antitrust rules, in general, are well beyond our

consideration here, but they typically prohibit both per se price fixing where otherwise competing providers jointly establish the prices they will accept and group boycotts where competitors jointly refuse to do business with an unattractive partner.¹ In the information and guidance offered by the Federal Trade Commission and the Department of Justice regarding the activities of provider networks, “joint pricing agreements will not be condemned as per se illegal if the participants have integrated their activities through the network in a way that is likely to produce significant efficiencies that benefit consumers and the price agreements are reasonably necessary to realization of those efficiencies.”²

When the initial antitrust safety zones were published, the forms of risk that were permissible among otherwise competing providers turned both on the type of financial risk taken (*e.g.*, capitation, percent of premium or withholds) and the percentage of providers in the networks. Another type of risk which the guidance allows is “global fees” or “all inclusive case rates.” Where there are agreements by a network:

[T]o provide a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined, payment, where the costs of that course of treatment can vary greatly due to the individual patient’s condition, the choice, complexity of length of treatment or other factors.³

That statement describes an affirmative safety zone

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¹For a brief but useful statement of many of these issues see Leibenluft, “Antitrust Issues Raised by Rural Health Networks” (Feb. 20, 1998), <http://www.ftc.gov/bc/ruralsp.htm>.

²“Antitrust Issues Raised by Rural Health Networks” 4 (Feb. 20, 1998), <http://www.ftc.gov/bc/ruralsp.htm>.

³“Statements of Antitrust Enforcement Policy in Health Care Issued by the Justice Department and Federal Trade Commission (Aug. 28, 1996), BNA’s *Health Law Reporter* 1309 (Aug. 29, 1996).

meaning that the regulators would not move to enforce if those factors were present. The case rate approach, as stated there, though, requires physicians of multiple specialties. There ought be no reason that physicians of a single specialty could not be put similarly at risk, and not even for complex care. Our CPG based payment in our scenario can work well for the congestive heart failure CPG discussed in terms of Medicare reimbursement. Acknowledging that other forms of risk may be equally as beneficial, the enforcers allow that they do not foreclose consideration of other models that put the providers at the dreaded “substantial financial risk.”

Whether such risk exists or qualifies in our model may, happily, be irrelevant since the enforcers allow yet a totally different, far more quality driven approach:

Physician network joint ventures that do not involve the sharing of substantial financial risk may also involve sufficient integration to demonstrate that the venture is likely to produce significant efficiencies. Such integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.⁴

Where the agencies have offered guidance but not a safety zone, they do not enumerate a checklist of qualifying characteristics. Rather they describe a scenario where they would not take enforcement action, absent other major problems. In addition, the physician network approach is also available for and they explicitly describe a multi-provider mechanism in the form of a PHO.⁵

Consider the following features of their elaborated

⁴“Statements of Antitrust Enforcement Policy in Health Care Issued by the Justice Department and Federal Trade Commission (Aug. 28, 1996), BNA’s *Health Law Reporter* 1309 (Aug. 29, 1996).

⁵“Statements of Antitrust Enforcement Policy in Health Care Issued by the Justice Department and Federal Trade Commission (Aug. 28, 1996), BNA’s *Health Law Reporter* 1322 (Aug. 29, 1996).

arrangement in comparison with our posited scenario: An IPA is established by a group of community physicians and it moves to implement systems to establish goals relating to quality and appropriate utilization of services by the IPA physicians. It regularly evaluates both individual and network aggregate performance in relationship to those goals and modifies individual participants' behaviors in relationship to the goals. The IPA itself will engage in case management, preauthorization of some services, and concurrent and retrospective review of inpatient stays. In addition the IPA develops and adopts practice standards and protocols to govern treatment and utilization of services, and actively evaluates the physicians' performance in relationship to those standards (*i.e.*, CPGs).

The regulators posit a significant capital investment in the systems necessary to the applicable reporting functions around clinical performance, patient satisfaction and individual and aggregate network behavior. The IPA provides detailed reports to payors about the performance measured. The IPA physicians are paid by health plans on a fee-for-service basis.

The IPA will retain an agent to develop a fee schedule, negotiate fees and contract with payers on behalf of the venture. Information about what participating doctors charge non-network patients will not be disseminated to participants by the IPA and the doctors will not agree on the prices they will charge patients not covered by IPA contracts.⁶

In terms of the participants and what they represent in the community, the IPA includes three geographically dispersed primary care group practices that together account for 25% of the primary care doctors in the hypothetical town. A number of specialists to whom they refer also participate. They constitute between 20% and 35% of the specialists in each relevant market. All the

⁶“Statements of Antitrust Enforcement Policy in Health Care Issued by the Justice Department and Federal Trade Commission (Aug. 28, 1996), BNA's *Health Law Reporter* 1312 (Aug. 29, 1996).

physicians participate in other managed care plans in the market. Here the regulators have stated that the price agreement is subordinate to and reasonably necessary to achieve the efficiencies posed by the clinical integration. In the PHO model, the story is almost exactly the same.⁷ It is noteworthy that the types of integration stated here are also the types of clinical integration noted by the HIPAA regulators under their discussion of organized health care arrangements. In fact an IPA acting in relationship to either a hospital or a health plan are the very few non-hospital based examples the HIPAA regulators offer.

What, then, can we conclude about the 1996 notions of the antitrust enforcers six years later with respect to forms of organizational functioning that would not bear undue scrutiny or enforcement? We know that they can and do take action against physicians who jointly bargain for fees without either clinical or financial integration, even when they claim the protection of having unionized. In a high profile action in Tampa, an organization of two dozen competing surgeons purported to use the infamous “messenger model,” but the enforcers did not share their interpretation of the messenger model rules, which explicitly prohibit joint negotiating.⁸ We know that the AMA’s short lived physician union, Physicians for Responsible Negotiation, was disbanded after eighteen months in light of the Supreme Court’s decision in *NLRB v. Kentucky River Community Care, Inc.*⁹ which held that health care workers in private hospitals could not join unions if their duties include drawing upon their professional training and experi-

⁷“Statements of Antitrust Enforcement Policy in Health Care Issued by the Justice Department and Federal Trade Commission (Aug. 28, 1996), BNA’s *Health Law Reporter* 1322 (Aug. 29, 1996).

⁸See Klein, “Justice Dept. Slaps Florida Physicians with Antitrust Charges,” *AMNews* (Feb. 15, 1999), http://www.ama-assn.org/sci-pubs/amnews/pick__99/pick0215.htm.

⁹*NLRB v. Kentucky River Community Care, Inc.*, 121 S. Ct 1861 (2001).

ence in supervising others.¹⁰ Federal investigations have been pursued in Connecticut and Ohio.¹¹ A Delaware investigation stopped a purported union in its tracks when its “messenger” bargaining with a major payer in the state, represented that he was speaking for 90% of the orthopedists in the state. The resulting settlement, trumpeted as an agreement allowing physicians to use third party messengers,¹² gave them nothing more than what the safety zones had stated would be legitimate some five years earlier. What’s a well motivated group of physicians to do?

Our hypothetical scenario falls squarely within the antitrust agencies’ published parameters. In settlements stimulated by enforcement of otherwise independent physicians’ efforts to bargain collectively for fees, the enforcers have reiterated their position that clinical integration is a viable alternative. In our scenario, CPGs drive payment, credentialing and a wide variety of other behaviors. The regulators do not take any position regarding the breadth of implementation of CPGs within a community. There may be issues of network size, and scope of the application of the CPGs; but these are not the essential concern. It is the linking of those CPGs to payment issues that is the biggest problem, in antitrust terms. Even there, it is the concerted action of the physicians alone, or too many of them joined together against the payer, in an effort simply to raise prices that incurs attention and enforcement. Where the arrangement is worked out among all the participants, the requisite conspiracy of one side against the other does not exist. Moreover, if our scenario plays out

¹⁰“Highlights of PRN Report to Delegates at AMA Annual Meeting June 15-21, 2001,” <http://www.4prn.org/kriver.html>.

¹¹Peterson, “Update on Joint Negotiations with Insurers,” American Academy of Orthopedic Surgeons, <http://www.aaos.org/wordhtml/bulletin/oct01/fline6.htm> (Oct. 2001).

¹²Albert, “Don’t Shoot the Messenger: Path Opens for Contract Talks,” *AMNews* (Nov. 12, 2001), http://www.ama-assn.org/sci-pubs/amnews/pcik_01/pr111112.htm.

as modeled, who would be the complainant to the antitrust enforcers?

Of course, there is always a chicken and egg problem in using clinical integration to cloak bargaining tactics in safety: how much integration and functionality must be in place before the physician-network can approach the payors? As we have seen so far, there is no bright line here, but, again, practicalities and the smell test tell us that “we’re fixin’ do to it” may be a statement about the per se nature of the antitrust risk and is not likely to satisfy the payors that the physician network is engaged in something more than naked price fixing. The bottom line, however, is the credibility of—and perhaps even more the motivation for—the joint action. Where physicians move to build a truly clinically integrated environment for quality purposes, so as to avoid having to engage in unnecessary documentation, to permit them to improve care to patients in all the ways that evidence-based medicine can, because they will be able to strengthen their doctor patient relationships and return to what makes medicine meaningful to them, truly the fee arrangements are subordinate to the quality purposes. To embark on clinical integration solely to be able to bargain for higher fees is folly, if not highly inefficient at best. It is the collaborative, coordinated, integrated behavior, where all the parties in the community are working together that makes the undertaking worth it. And in that case no matter who goes first in negotiating terms, or whether the health plan facilitates the development of the infrastructure described by the antitrust regulators, which party moves the physicians along the continuum to true clinical integration will not matter. Our hypothetical market is a win-win for all concerned under the antitrust rules and otherwise: The community gets better, more evidence based care. The parties are not adversaries in antitrust terms; and the fee setting aspect of the arrangement whether case rates, global rates, fee for service or something else, can be structured to be subordinate to the true purpose which is to make better quality happen faster.

§ 13:16 Conclusion

To create truly quality-driven healthcare in a market, or community, or even a single system, as in the scenario that has anchored this consideration, is an enterprise that raises a host of profound challenges, many of them operational. To make our story real requires new forms of workflow in hospitals and physician offices including such changes as Drop In Group Medical Appointments¹ which are conducted in less scheduled office practices, and differently organized examination rooms,² and better systems for patient safety in hospitals,³ and better collaboration and coordination merely to improve pure clinical processes of care such as that in the national (and even international) quality improvement project known as “Pursuing Perfection.”⁴ None of these is a small task by itself.

But that would not be enough. The landscape described requires cultural, organizational and leadership changes to engender a clear and committed vision tied to self renewing processes to make its aspirations real. At its core, above all, it requires good science which reflects the application of what we know to be right, which, by definition, changes over time. And, it should be observed, it also requires skills and support for the psycho-dynamics of strong, meaningful doctor-patient

[Section 13:16]

¹Walpert, “Patients Tired of Waiting? Try These Strategies,” *ACP-ASIM Observer* (Oct. 1999), <http://www.acponline.org/journals/news/oct99/waiting.htm>; Domin, “Doctors Find Quality Time with Patients in Groups” (Oct. 6, 2000), <http://www8.cnn.com/2000/HEALTH/10/06/doctors.time>; Noffsinger, “Enhance Satisfaction with Drop-in Group Visits,” http://www.hippocrates.com/February-March2001/02features/02feat__digman.html.

²Bagley, “Building for Tomorrow: The Idealized Design of Clinical Office Practices,” *Fam. Practice Mgt.* (May 2000), <http://www.aafp.org/fpm/20000500/13buil.html>; and <http://www.ihl.org>.

³See <http://www.leapfrog.org>.

⁴http://www.ihl.org/pursuing_perfection.

relationships that stand at the frontlines of all of health care delivery. The range of things necessary to make the American health care system a better one characterized by singularly improved quality is considerable.

To embark on this journey, from where we are today to where we need to be, and can be, is not merely a quest for a mythological talisman. It is a responsibility that comes with what health care is about, its real purpose. Those of us who come to the work of health care quality from a wide variety of perspectives are often confronted with the plaint of “but where is the business case for quality?” While in a world of finite health care dollars this is understandable, and the expense of quality processes has to be taken into account, the question is almost beside the point—there is no other case in health care than the one for quality. In the scenario we have considered here, greater efficiencies and lower administrative costs cannot help but emerge from more streamlined, standardized and clinically relevant management systems by comparison with the fragmented, error prone, unsatisfying, custom-crafted delivery system familiar to us today. The business case is inherent in the operation of the components that make our scenario a unified, truly clinically integrated, understandable system, based on science. Yet there is nothing in the construct which assumes its uniform application, in the same way, in every market, or even within markets or across the country. It merely provides principles of operation which guide the activities down whatever specific path the travelers choose.

But, the thrust of this consideration has been on the laws which, however well intentioned at their inception, we now see have added unnecessary complexity and a crushing, burdensome and meaningless weight to the task of making quality happen.⁵ The major regulatory programs in reimbursement, anti-referral and

⁵And, there are other ancillary legal issues not addressed here relating to, for example, how to implement within medical staff organizations systems which may recognize differently the physi-

fraud and abuse, and privacy are excessive, intrusive and directly noxious if not affirmatively toxic to the management simplicity we need to deal with the inherent complexities of health care delivery and science. Only the antitrust laws hold out the promise of receptivity to a more idealized quality orientation that will permit those who are engaged to do well by doing good.

To make this journey we need to travel lighter. We need multiple pathways, even in the national insurance program of Medicare. There is much that the law imposes on this passage today which is outright superfluous and restrictive. Still, as we have seen, most of the existing terrain is navigable, but not without tedious and careful baggage management and course plotting. Wouldn't the trip be easier if those who are in the business of setting the ground rules, namely Congress and the regulators, could conceive of their role as one which requires a consistent platform of unified purpose and science, explicitly supporting and depending upon the use of evidence based clinical practice guidelines as the sextant, as they influence the course of the health care system?

cians who are on board for various elements; how licensure laws restrict personnel assignments or how guidelines are developed, translated and implemented; or how performance measurement systems are designed and their results reported. All will raise legal concerns.

