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The Doctor-Patient Relationship as the Business Case for Quality: Doing Well By Doing Right

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ABSTRACT: The idea that healthcare quality in America has lagged behind optimal levels has been a central national policy issue since at least 1998. Reform efforts, however, have failed to acknowledge the critical and unique role physicians play in making quality initiatives real. This Article argues physicians are at the core of any effort to propel quality forward in a significant way and, therefore, must be taken into account directly and without apology. The Article examines the quality-accountability context present in this country. It addresses why the physician nexus on these issues is vital for real change to take place and sets forth a clear statement of what is essential to support the doctor-patient relationship in any quality agenda. Finally, it reiterates the author's previously proposed five principles for quality, as well as her unified field theory of quality, all of which are designed to advance quality in a very different way.

The idea that healthcare quality in America has lagged behind optimal levels has been a central national policy issue since at least 1998. Identifying major quality problems of misuse, underuse, and overuse of care that do not reflect scientific evidence, the National Quality Roundtable found that

> [a]t its best, health care in the United States is superb. Unfortunately, it is often not at its best. Problems in health care quality are serious and extensive; they occur in all delivery systems and financing mechanisms. Americans bear a great burden of harm because of these problems, a burden that is measured in lost lives, reduced functioning, and

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> wasted resources. Collectively, these problems call for urgent action.[1]

Two seminal studies from the Institute of Medicine (IOM), *To Err is Human*[2] and *Crossing the Quality Chasm,*[3] have drawn further attention to these concerns.[4] The development of the Leapfrog Group[5] and the advent of pay-for-performance (P4P) programs[6] are evidence that the IOM's positions are not merely concerns of policy pundits, but rather are real calls to action that are now being heeded.

Nonetheless, little attention has been paid to the most significant reason that quality has lagged in America: failure to acknowledge the critical and unique role physicians play in making quality initiatives real. In addition, although P4P has been posited as furthering a business case for quality, in actuality, it misses some essential points. This Article elaborates on the quality-accountability context that has arisen in this country. It addresses why the physician nexus on these issues is vital for real change to take place. In addition, it sets forth a very clear statement of what is essential to support the doctor-patient relationship in any quality agenda. Further, it offers five principles and a theory, all of which can advance quality in a very different way. Finally, the Article describes what the proposed theory can accomplish, its limits, and why it should ultimately be implemented.

I. The Quality Context

It is undeniable that quality is on the public policy radar screen. The Leapfrog Group took the buying power of 145 employers of thirty-five million Americans and brought that power to bear in a purchasing process that is explicitly oriented around quality-motivated principles. This was truly a groundbreaking undertaking. The Center for Medicare & Medicaid Services' (CMS) Hospital Voluntary Reporting Initiative,[7] its Doctor's Office Quality project,[8] and its versions of provider P4P,[9] are yet further expressions of disquiet concerning how quality should advance. The multiple demonstration projects and pilot initiatives addressing quality issues, enacted as part of the Medicare Prescription Drug and Modernization Act, are further symptoms of the public policy focus on quality.[10]

Yet these very recent undertakings do not take into account the pre-existing and wide-ranging hodge-podge of federal and state laws already aimed at improving quality. Federal law regulates quality in some significant ways. The evolution from Professional Standards Review Organization program[11] to the PSRO program[12]

to today's Quality Improvement Organizations (QIOs)[13] demonstrates the fundamental shortcomings of the Medicare and, to a lesser extent, Medicaid programs. These programs require a mechanism to assure that services are medically necessary, meet professionally recognized standards of care, and are not capable of being provided more appropriately in a less expensive facility.[14] QIOs serve as the source for public information about performance, particularly with respect to home health agencies and skilled nursing facilities.[15] This scheme was created as part of the government's response to the *Crossing the Chasm* value of "transparency."[16] CMS' Doctor Office Quality project is being implemented through the QIOs in Iowa, New York, and California.[17] QIOs are engaged in regionally focused quality studies to improve performance. They retain, however, their powerful authority to influence the federal sanctions process by recommending sanctions against providers for substantial or gross and flagrant failures to comply with norms, criteria, and standards.[18]

The Emergency Medical Treatment and Labor Act (EMTALA)[19] was also adopted as a means of quality protection. EMTALA prevents the transfer of patients presenting for emergency services who have not had an appropriate screening evaluation and who have not been stabilized.[20] In the case of a woman in active labor, the statute prohibits transfers entirely, except under limited circumstances.[21]

Throughout the history of the Medicare program, facilities and institutions have had to comply with baseline conditions of participation to retain their eligibility to receive Medicare funding.[22] Over time these conditions, for hospitals in particular, have gone further in their quality implications. Hospitals have also incorporated the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) panoply of quality initiatives. These initiatives were adopted by virtue of "deemed" Medicare qualification based upon JCAHO accreditation.[23] Another example of federal attention to egregious quality problems is the threat of Medicare participation termination and the exclusion from federal programs experienced by a Tenet hospital in Redding, California. The hospital faced exclusion because of unnecessary surgeries and admissions or, in the new quality nomenclature, "overuse."[24]

Medicare managed care programs have their own highly detailed quality requirements, found in the Quality Improvement System for Managed Care (QISMC) and Quality Assessment and Performance Improvement (QAPI) programs.[25] The Healthcare Quality Improvement Act,[26] which was adopted as a means to bolster aggressive peer review, is also a quality-regulating statute. Protec-

tion from antitrust liability is only available when the peer review entity makes its judgment on the good-faith belief that it was in furtherance of quality, and when the peer review entity reports the limitation on clinical privileges or staff membership to the National Practitioner Data Bank. Access to this data bank is intended to both warn and facilitate appropriate inquiries by institutions considering the addition of a physician to their ranks.

Moreover, quality is now unequivocally a fraud and abuse issue and is increasingly a focus of enforcement attention. The initial enforcement action in the new quality era arguably came with the case of *United States v. Tucker House*.[27] In this case, the serious decubiti (bedsores) experienced by nursing home patients demonstrated that these patients had not received appropriate care. This occurred despite all of the safety net initiatives Congress enacted, reaching back to the Consolidated Omnibus Budget Reconciliation Act (COBRA) in 1986.[28] When the government learned that one of the exacerbating factors in aggravated decubiti was malnutrition, they fashioned a novel enforcement theory. The government claimed that every day of service in the skilled nursing facility that the program paid for was a false claim because the home represented in each claim that it was providing all of the services incorporated in the per diem payment. Those services implicitly included feeding the patients. The settlement in the case not only garnered hundreds of thousands of dollars, but also required the home to follow the Agency for Healthcare Policy and Research (AHCPR) guidelines on treating decubiti[29] and has served as a model in at least forty additional settlements nationally. In addition to *Tucker House*, the criminal charges against United Memorial Hospital[30] for longstanding, aggressive treatment by pain management physicians that resulted in medically unnecessary admissions represented a significant scaling up in criminal enforcement of relevant quality obligations.

Multiple bases exist under current federal law to exclude providers or charge them with civil money penalties for quality failures. Providing items or services to patients that are substantially in excess of the patient's needs, regardless of eligibility for benefits under Medicare or Medicaid, can lead to exclusion from the federal programs.[31] When providers render services of a quality that fails to meet professionally recognized standards of healthcare, the government may exclude the providers.[32] In addition, if a person submits claims for a pattern of items or services that the person knows or should know are not medically necessary, the government may assess a penalty of $10,000.[33] Further, if an individual provides false or misleading information that could reasonably be

expected to lead to a premature discharge, a civil money penalty of $15,000 can be assessed.[34] Finally, if hospitals provide payments to physicians to reduce services, even if that reduction is off of a baseline of overuse, a civil money penalty of $2,000 can be assessed.[35]

Federal law also targets physician incentive plans that put physicians at substantial financial risk, possibly motivating underutilization.[36] Even the Stark Law[37] and the Anti-Kickback Statute[38] can be seen as quality oriented insofar as they address utilization. The Stark Law and the Anti-Kickback Statute guard against the incentive physicians may have to overuse or misuse services because of the financial benefit they may receive for referring a patient to an entity with which the physician has a financial relationship. The Office of the Inspector General has increasingly targeted quality issues in both its 2003 and 2004 Work Plans.[39]

These federal initiatives are not all that define the quality regulatory environment. There is more. Throughout the country, state managed care reform legislation, purporting to address quality issues, has been enacted in light of managed care backlash.[40] Further, more and more states statutorily require the public reporting of quality data.[41] Finally, states have their own anti-referral laws, which frequently mirror the Stark Law and the Anti-Kickback Statute.[42]

Despite the detail and broad sweep of these quality-focused regulations, they have not improved healthcare. They have not engaged physicians or persuaded them that quality initiatives merit their attention. Physicians see most of these penalties, regulations, sanctions, and disincentives as enormous hassles aimed at the miscreant few among whom they do not number themselves. Indeed, if these laws and programs had engaged physicians, we would not be considering today whether there is a business case for quality.

II. The Physician Nexus

Why focus on physicians? Although rarely admitted or even acknowledged in a world in which nonphysician practitioners continue to expand their scope of practice under state laws, it remains the case that physicians retain plenary legal authority. They have the broadest scope of legal authority of any clinician in the healthcare system. It is a truism that the most expensive form of technology invented to date is the ballpoint pen with which physicians write their orders. Hospitals and managed care organizations (MCOs) neither admit patients nor discharge them. Most patient services are called into play because of a physician order. Moreover, many of the ancillary practitioners who do pro-

vide services in our increasingly complex healthcare system do so through a physician order.

Patients experience the healthcare system primarily through their interaction with a physician. This is why the first question potential subscribers ask about a new health plan is, "Is my physician in the network?" Not only do physicians perform many of the most critical and intimate procedures the patients will experience, but they also serve as interpreters of the system, make referrals and recommendations to other organizations and practitioners, and even explain the insurance benefits available to the patient. Physicians are also fundamental because of their relationship to other healthcare organizations and institutions.[43] How did physicians come to enjoy this position?

The essential transaction in which a physician engages with a patient is different from all other clinical interactions in the healthcare system. Why do patients seek out physicians and what is the essence of the physician role? "[Physicians] transform information into meaningful explanations of the present, predictions of the future, and changed futures, mainly for individual patients, and sometimes for whole populations."[44] This characterization of the essential activity in which physicians are engaged has been recharacterized and adopted by another commentator as follows:

> [T]he fundamental nature of the transaction that takes place between physician and patient, as complex, multifaceted, and enigmatic as it is, can be captured in just three questions that people seek answers to when they are sick . . . . [P]eople basically look to their physicians to 1) explain nature: "What is happening to me?;" 2) predict nature's future: "What's going to happen to me?;" and 3) alter nature's future for the better: "What can be done to improve what happens to me?"[45]

As Doctor James L. Reinertsen says,

> We take information about health and transform it to a higher order of information, not just as an intellectual exercise, but to satisfy the three fundamental needs of explanation, prediction and change. We can do other things in the course of our day, but all are secondary to this primary task.[46]

The IOM adopted this profound and critical insight in *Crossing the Quality Chasm*, stating that "the transfer of knowledge is care."[47]

High-quality care, therefore, is care which makes that transfer in the most effective way. To do so entails complex interactions by which principles of science are applied to the patient's individual clinical and social circumstances. Effective transfer can only occur when the physician can bring to bear in his relationship with the patient two essential factors—time and touch. These factors are critical to a physician's approach and treatment of a patient. Time and touch affect a physician's ability to grasp the subtleties in each patient's situation. These subtleties are significant when fashioning an effective approach to the patient. In addition, time and touch are essential to optimal communication, which implements appropriate treatment. To customize the application of science, the physician must listen, explain, examine, comfort, teach, treat, perform procedures or surgery, and otherwise address the specific and variable needs of the individual patient. This "touch time" is what defines the art of medicine.

The fundamental policy challenges to improve quality, therefore, are: (1) to eliminate those aspects of the current environment that steal touch time from the doctor-patient relationship; and (2) to support those measures that enhance optimized time and touch.

III. Hazards to Time and Touch[48]

A. Clinical Time Stealers

One of the most frustrating aspects of the current practice environment for most physicians is the time they must devote to irrelevant documentation. The documentation demands of evaluation and management codes (E/M), the failure to comply with which can lead to false claims exposure, has nothing to do with the clinical treatment of the patient. This documentation has been developed purely for post-payment auditing purposes to verify that the level of code and the reimbursement associated with it were appropriate to the service. Similarly, the documentation of the medical necessity of specific services in the course of treatment is neither necessary nor clinically useful, but is required primarily for post-payment auditing. The litany of ministerial minutia the physician must engage in for other entities in the system to get paid, such as certificates of medical necessity (CMNs) for parenteral and enteral nutrition[49] or durable medical equipment,[50] also steals time that might otherwise be spent transferring knowledge and engaging in healing relationships. The American Medical Association (AMA) reportedly has data showing that some physicians spend one hour of administrative time completing forms and the like for each four hours of clinical time.[51]

Health plans impose their own administrative burden. The process of obtaining prior authorizations in a health plan is time consuming and annoying. Although the financial incentives of capitation were supposed to motivate appropriate clinical behavior by physicians, studies show that MCOs have been unwilling to trust them, viewing the incentives as barely adequate to motivate change. Instead, virtually all MCOs reviewed use additional, cumulative safeguards against utilization, including prior authorization, encounter forms, review of non-emergency admissions, concurrent review of hospital stays, discharge planning, ambulatory care review, and clinical practice guidelines.[52] Physicians must engage in repetitive and redundant credentialing when they apply to multiple MCOs and hospitals, even in the same region. This has been so burdensome that an entire industry of credentials verification organizations has developed to perform this function in a more centralized and efficient manner. These organizations now play such an important role in credentialing that the National Committee for Quality Assurance (NCQA) has developed a certification program to evaluate their quality.[53]

Other time stealers include more intense consumerism in the form of direct-to-consumer advertising; patient use of alternative therapies, which they may or may not reveal to their physicians; and extensive information seeking of quite variable quality on the worldwide web. These transactions take physician time because the patient often requests the physician to confront this data. The mere fact that patients respond to these questionable forms of health information may itself be a sign of patient dissatisfaction with the quality of interchange they experience with their physicians.

The expanding shift to disease management approaches throughout the country[54] is intriguing to physicians. They frequently view it, however, with skepticism, as yet another time stealer and unlikely contribution to their efficiencies. The sheer explosion of the knowledge base physicians must manipulate in their treatment of the patient has itself become essentially unmanageable.[55] The difficulty of having available the best evidence of how to treat a patient, combined with the fact that physicians, by their own choice, practice clinical science as an "individual sport" instead of a "team sport,"[56] further detracts from time and touch.

B. Administrative Time-Stealers

Clinical practice demands are not the only hazards to time and touch. Administrative demands in the form of hospital-medical staff responsibilities and service on hospital committees consume considerable amounts of time. Physicians are so beleaguered in

the challenges that they must confront in their own practices that service in the leadership of medical staffs is no longer seen as a matter of prestige, but merely as a time drain. The ability to muster a quorum at medical staff meetings has become a challenge throughout the country.[57]

Messaging and workflow interruptions, in large part associated with pharmaceutical management, have also become a major time sink. Physician meetings with pharmaceutical representatives and pharmacy benefit managers are time-consuming. In addition, the sheer complexity of managing the patients' prescription needs is troublesome, both in terms of writing and renewing prescriptions, and in dealing with inconsistent formularies. Even in the current environment, however, defensive medicine retains a stronghold on physician practice. Physician anxiety about malpractice[58] not only produces medically unnecessary services, but is an administrative burden because it is a response to a perceived external, clinically irrelevant mandate. Defensive medicine leads to irrelevant procedures that waste time in the doctor-patient relationship and has frequently been mentioned in the debates surrounding the malpractice insurance crisis and the need for tort reform.[59]

Despite this panoply of time demands, the biggest hazard to time and touch in the doctor-patient relationship by far is the payment systems with which physicians must contend.

IV. Payment

Virtually all of today's physician payment mechanisms fail to speak effectively to the way physicians solve clinical problems. In addition, they barely incorporate what the evidence reveals is appropriate quality, and add to the administrative burdens that physicians must bear.

The two primary forms of payment that have defined the physician reimbursement environment for the last thirty years have been fee-for-service and capitation or its derivatives. While more familiar to physicians because of its longevity, fee-for-service is no more clinically relevant to the way physicians practice than any other system. Fee-for-service payment systems carve up each element of care into defined units of service. Each is then associated with a charge or a payment. Obviously, the more services rendered, the more payment will be received.

Capitation, on the other hand, is an insurance principle that emanates from actuarial concepts of the risk of the incidence of disease in the population that is covered. It takes into account a

relatively unspecific estimate of what the use of service will likely be based on past patterns of care. Capitation, however, can only reflect the services that were rendered in the past projected forward, regardless of the quality of the services, because it is predicated on actuarial and not clinical principles. The physician, or the group within which he practices, is paid for an assigned panel of patients, whether or not they ever present for care. As such, it is to the physician's economic advantage to have assigned to him healthy people who never use his services. Every time a physician provides care to a patient, dollars are depleted from the capitation payments the physician receives. Capitation incentives, like an allowance paid to a teenager, are blunt and broad. That is, all they stand for is the value of a healthy population and the hope that the physician will think twice before rendering services to one patient at the potential expense of a future patient who may have greater needs.

The perverse aspects of these two fundamental forms of payment have been succinctly characterized by a federal court:

> A health maintenance organization (HMO) offers for a fixed fee, as much medical care as the patient needs. Providers using traditional fee-for-service methods, by contrast, charge for each procedure. Each method creates an unfortunate incentive: a physician receiving a fee for each service has an incentive to run up the bill by furnishing unnecessary care, and an HMO has an incentive to skimp on care (once patients have signed up and paid) in order to save costs. Each incentive encounters countervailing forces: patients, or insurers on their behalf, resist paying the bills for unnecessary services, and HMOs must afford adequate care if they are to attract patients. HMOs also have reason to deliver excellent preventive medicine. Prevention may reduce the need for costly services later. Competition among the many providers of health care, and between the principle methods of charging for that care, affords additional protection to consumers.[60]

Other variants on capitation include: (1) contact capitation, where the specialist is paid on these actuarial principles, not for an assigned panel, but as each patient presents for specialty care; (2) episode of care, where a specialty is assigned a budget to be distributed on a periodic basis to all of the specialists in the pool, depending on how many episodes of care were triggered (each

episode is paid at the same rate, regardless of the volume or scope of the services rendered); and (3) global capitation or percent of premium, where the provider, network, or group is paid for services he is assigned beyond his or its own, using an actuarial calculation of rate construction.[61]

The new phenomenon that has emerged in the last four years, with its greatest impetus in 2003, is the P4P phenomenon. Through P4P, hospitals or physicians are paid some add-on amount of money for rendering services that further quality.[62] These new payment methodologies, including those of CMS, fundamentally fall into three categories: (1) where there is a threshold of behavior that garners a bonus (e.g., physicians who meet the NCQA Diabetes Provider Recognition Program standards get paid $100 per diabetic per year in the Bridges to Excellence Program [BTE]);[63] (2) where the pool of providers is arrayed normatively, compared to each other, and the best performers get paid a premium based on their relative status with respect to other performers (*e.g.,* CMS Premier Hospital Quality Incentive Demonstration[64] and Central Florida Healthcare Coalition);[65] and (3) where the providers are offered a potential pool of money which they can only receive if they meet certain thresholds *and* provide savings compared to a control group (*e.g.*, CMS Physician Group Practice Demonstration Program).[66]

There is no question that in P4P, where additional payments are made on top of other monies they are already receiving, physicians will experience increased revenues in return for some measure of demonstrated quality. The real question, however, is whether the efforts necessary to earn the additional money are sufficiently rewarded by the amount of payment received. For example, it is estimated by the BTE program that it will take fifteen minutes to cull data from a physician office record and self-report it to the NCQA Diabetes Recognition Program with which BTE is linked.[67] Although the average payment made in the first round of payments under this program was claimed to be in the thousands, and the program states that some physicians could earn up to $20,000 in bonuses, this would mean the practice had 200 diabetic patients. To abstract the data for those patients, even at merely fifteen minutes a chart, would entail fifty hours of work. The BTE program also contemplates two other modules for cardiac care and other office processes, which will impose additional administrative demands. These demands have not yet been quantified. In addition, almost all of the P4P programs are oriented towards under-used services, both because data have shown that Americans get only fifty-five percent of what science tells us is appropriate for quality[68] and be-

cause it is easier to focus on what has not been done, rather than what should not have been done.

Thus, most of the physicians who would be paid under these P4P programs will have increased revenue, but they will also have increased expenses in terms of clinical staff time and supplies and equipment necessary to deliver the underused services. For those physicians who are overutilizing services, revenues would decrease in a fee-for-service environment but their base pay would stay the same in a capitated setting. Their expenses, however, would decrease in both contexts because they would not have to use the staff time or the supplies and equipment that would produce the overused services. These P4P programs do not adequately address the issue of misuse. In addition, many of the P4P programs make payments based on data produced by the health plans. Reports indicate that physicians are sufficiently concerned about the inaccuracies in the data health plans produce, upon which their bonuses are based, that they engage additional staff time in checking the data.[69]

Physicians are expected to respond to the incentives of the payment systems in order to render quality services to their patients. Unfortunately, these incentives do not necessarily get us where we need to be. Five overarching principles would help.

V. Five Principles to Quality

The following five principles would help improve quality:

(1) Standardize;
(2) Simplify;
(3) Make Clinically Relevant;
(4) Engage the Patient; and
(5) Fix Public Accountability at the Locus of Control.

Each of these five principles is important in putting the healthcare system more clearly on a pathway to improved quality. Bringing all five of these principles together would revolutionize healthcare delivery in this country.[70]

A. Standardize

Standardizing to the science that is clearly standardizable in physician delivery of care would increase the delivery of evidence-based medicine (EBM). Standardization ought not to be limited to clinical processes, but should include the documentation of care as well. To templatize delivery of care to a congestive heart failure patient,

for example, so that the essential steps of treating the patient are delivered consistently over time to all congestive heart failure patients in the practice, would inevitably return time to physicians, because the documentation requirements today are not just a waste of time but physician implementation is often idiosyncratic, inefficient, and frequently incomplete. The author frequently asks physicians, "If I could save you three minutes a patient and improve your documentation, would you do what I suggest?" In today's environment, this proposition is met with uniformly positive enthusiasm. Physicians should seek to standardize to the science as much as possible in order to be able to "custom craft' the art of care delivery to the individual patient in those activities of "touch time." These areas define the essence of a doctor-patient healing relationship.[71]

B. Simplify

The wide variety of financial incentives, contractual obligations, documentation requirements, utilization review systems, medical management programs in managed care entities, and administrative burdens that have no relevance to the delivery of EBM should be removed from the physician practice environment. The misery of being measured by widely disparate performance measures and principles of care is behind the agreement among the five leading health plans in Minneapolis to use the same practice guidelines.[72] Disparate multiple measures also inspired California's Integrated Healthcare Association's P4P program, which uses common performance measures among participating health plans.[73] Similarly, in the hospital context, to simplify what physicians are asked to do would give time back to physicians, freeing time for their highest and best use—caring for patients. Sometimes this means drawing on the skills and services of ancillary clinical practitioners in a team-oriented system. In ways far too numerous to list here, the current environment is simply too complex.

C. Make Clinically Relevant

In payment methodologies, documentation requirements, design of information technology support mechanisms, manpower resource planning, and even hospital recruiting for clinical staff, clinical relevance should be used far more as the touchstone for all decisions around how care will be delivered, taking into account those services that patients need in clinical terms. One of the most dramatic examples of the dilemma of failed clinical relevance was the refusal of the entire medical staff at the Cedars Sinai Medical Center in Los Angeles to use the multimillion-dollar computer program for physician order entry. The physicians felt the program

was dangerous, time consuming, and unwieldy.[74] There is much that can be done to improve a hospitals' own quality performance, if these five principles of time and touch were incorporated into those delivery processes.[75] As demonstrated, most of the demands on physicians that steal time and touch from patients stem from the fact that the systems with which they must contend have no clinical relevance to the objective of EBM.

D. Engage the Patients

This principle, which entails the "patient-centeredness" values extolled by the IOM in *Crossing the Quality Chasm*,[76] also has legal significance. It has long been shown that the most powerful risk management technique to prevent malpractice litigation is a good doctor-patient relationship. Patients do not sue the physicians whom they love. An emphasis on touch time, therefore, can only serve as a bulwark against frivolous malpractice claims. Moreover, an engaged patient is far more likely to follow physician's orders and perform his part of the EBM transaction. In Vermont, consideration of an engaged patient model for chronic care of diabetic patients has been proposed for implementation throughout the state based on the expectation of better care and more efficiency.[77] In Whatcom County, Washington, a similar approach to truly engage patients in the treatment of diabetes and congestive heart failure projected not only significantly improved outcomes, but real cost savings to the system as well.[78]

E. Fix Accountability at the Locus of Control

In the new era of "transparency"—to make known the way in which care is being delivered, whether good or bad—physicians have been resistant to, and anxious about, the way in which their story will be told in report cards. This paranoia is not a sign of mental defect. Physicians claim that the data health plans maintain about them is "junk"[79] and they are being measured by factors that they cannot control. If we were to bring to bear the previous four principles, however, it is likely that physicians would be far more willing to be held publicly accountable for those aspects of the doctor-patient relationship that they can control. Physicians are capable of controlling only two fundamental aspects of care: (1) the application of the science that is appropriate to their patients' needs; and (2) the quality of their doctor-patient interactions. Many of the other aspects of healthcare report cards, in fact, do not reflect an individual physician's performance, but rather the performance of his group, his network, or the hospital at which he practices. Accountability and reporting at those levels should be similarly refined and focused.

These five principles reflect the new values that surfaced in the period of time after *Crossing the Quality Chasm*. At their core is the strong weight given to science, or EBM. We need systematic statements of the current evidence in order to achieve the greatest standardization possible. This is why there is a call for more EBM and for the creation of good clinical practice guidelines.[80]

The distinctions between EBM and clinical practice guidelines (CPGs) turn essentially on the quality of the evidence on which the algorithm is based. EBM involves systematic review of the peer reviewed literature to determine what the evidence shows. Although many CPGs incorporate EBM, others are based purely upon consensus.[81] For the purposes of this consideration, it is irrelevant whether we use EBM or CPG. In today's world, almost any degree of order predicated on reasonable science will advance the state of the art better than the chaos that characterizes the current environment. Taken together, the *Crossing the Quality Chasm* values are calling for evidence-based care combined with patient-centeredness made known in transparency or report cards. Although the IOM assiduously avoids cost and payment issues necessary to implement its values and avoids the time stealing policy bedlam we have reviewed, a consistent payment system is necessary. To address all of these factors together, we now come to a theory.

VI. Gosfield's Unified Field Theory

Originally propounded in 1997 and published in 1999,[82] this theory found its impetus in my observation that all of my physician clients were wildly angry all the time about everything, to such an extent that they were unable to help themselves. In trying to understand the anger, I began to identify as contributory causes many of the hazards to time and touch that have been enumerated here. Physician anxiety does not turn on a perceived loss of autonomy alone. Rather, there is a very complex confluence of disparate policy, legal, and market forces that whipsaw physicians in their daily lives, to which they respond as if these forces are unrelated to each other. What was needed, I thought, was a unitary platform upon which more of their activities could be based. Thus, I developed the concept of a "unified theory" to provide a solid and consistent foundation for most of what they do, while simultaneously advancing quality. Bringing together the new values of the healthcare system, with the participation of my colleague, Dr. James L. Reinertsen, we have further refined this theory in light of our five principles to incorporate the following nine elements:

1. Select a clinical practice guideline;
2. Translate it into applicable ICD-9 and CPT codes;
3. Note the documentation standards in templates;
4. Document the full pathway of care (not just physicians);
5. Accommodate appropriate deviation;
6. Engage the patient;
7. Price the services;
8. Measure compliance; and
9. Analyze and refine.

(1) To use CPGs to drive payment and other behaviors, one must start with a good CPG that meets the eight attributes enunciated by the IOM. These attributes were devised when the IOM was advising AHCPR on how to implement its then new authority to create guidelines, performance measures, and standards of quality.[83] There are now a host of CPGs available, as well as a government-sponsored Web site that is searchable and allows comparison among guidelines for a condition or treatment.[84]

(2) Most good CPGs can be translated into their applicable ICD-9 and CPT codes. This is important because the current fee-for-service contexts, notably Medicare fee-for-service, permit clinically relevant documentation that supports the medical necessity of the services as well as enumerates the care actually provided to each individual patient.

(3) These analyses of what a CPG stands for in terms of claims reporting can be standardized into documentation templates that reflect EBM and save time by virtue of their standardization.

(4) In many instances, considering the full pathway implied by the guideline can add greater strength and scope to its application. For example, giving real thought to which clinician is the highest trained, least expensive person to provide an element of a guideline saves physicians for their highest and best use and facilitates a team approach to delivering care. This can have other salutary ramifications, including enhanced patient safety due to shared clinical responsibility and the safeguard of care delivery in accordance with science. Moreover, consideration as to when to refer a patient for more specialized care can also be accommodated in this way. The guidelines promulgated by the Institute for Clinical Systems Improvement, for example, often make reference to when the patient should be referred to a specialist.[85]

(5) Accommodating deviations addresses the frequently raised resistance to the application of CPGs as "cookbook medicine."

As enunciated by the IOM, however, good CPGs contemplate the typical clinical variations one might expect, as in a patient who has a co-morbid condition. For example, the typical congestive heart failure patient may also have diabetes and hypertension. A physician might follow one preferred regimen in the absence of those exacerbating factors, but would have to follow a different branch if those other conditions exist. These are well-known circumstances and can easily be taken into account. Further, there will be instances, including socioeconomic circumstances, patient preference, or allergy to the drug of choice, when the treatment of the patient should deviate from the guideline-based norm. This can be accommodated as well under this theory.

(6) Engaging the patient in accordance with *Crossing the Chasm* principles is an important element of enhancing the doctor-patient relationship, gaining patient trust, and assuring the patient's understanding of the treatment regimen, thereby enhancing quality.[86]

(7) Perhaps the most revolutionary aspect of this theory is its utility for pricing and, therefore, paying for services in an entirely different way. There are virtually no physician practices, nor even health plans or hospitals, that can tell you how much it costs to treat a patient for a condition. While a very sophisticated group practice administrator may be able to recount all of the relevant expenses associated with the operation of the practice, very rarely are these expenses quantified in clinical terms. An analysis of the cost of providing the services within a national CPG can aid in constructing a budget for delivering that care. For example, in the Institute for Clinical Systems Improvement guideline for the treatment of asthma, the node in the algorithm addressing an interval evaluation establishes that the services to be provided are: a medical history, assessment of the asthma triggers or allergens, a physical examination, measurement of pulmonary function by spirometry or peak expiratory flow rate (PEFR), and consideration of consultation and/or allergy testing.[87]

When analyzed for its cost components, this guideline includes services by clinicians in taking the history and assessing the asthma triggers as well as performing the physical examination. This could be done by a nurse, a nurse practitioner, a physician's assistant, or the physician. Some aspects of the history can be recorded by the patient himself in a form or by nonclinical personnel recording patient responses to questions. In addition to the time of the clinical personnel, there is the cost of the examination table, the paper covering it, and the gown the patient wears during the examination. Still further, there is the spirometer and the flow meter to evaluate

the PEFR. These pieces of equipment represent the cost of delivering the services, along with the general overhead of the office.

This kind of cost accounting is not difficult to do conceptually, but it is virtually absent from the current healthcare marketplace. There are complex variables associated with the quantification of the dollar value of physician time. Still, to bring to bear this kind of an analysis, even in part, for a range of conditions in a practice, hospital, or network, would eliminate much of the most troublesome elements that exist in the current payment system. Whether the services are paid for on a case rate basis, where the entire algorithm over a period of time is paid for at a negotiated rate reflecting these costs, or on a fee-for-service basis, the cost dialogue and price dialogue in this context is radically different.

The next two steps, measuring compliance and analyzing and refining, are techniques to evaluate what can be improved in the delivery of care, who is complying with science more effectively as a clinician, where there may be problems within the algorithm itself, and where there are additional opportunities to improve. In addition, other conclusions might be drawn from having measured the actual delivery of care in accordance with a standardized protocol. It is well known that you cannot improve what you do not measure—because without measurement and evaluation, you cannot know whether improvement has occurred.

The financial margin implications of this approach cannot help but be better than those in existence, including the P4P programs already briefly described. To the extent that physicians standardize their documentation, time will be saved. Saved time equates to lowered expenses. Thus, standardization, even in the absence of payment change, is worth achieving to regain wasted time. This payment method will lead to decreased expenses for the overutilizing physician and increased expenses for the underutilizing physician. Whether revenues increase or decrease depends on the payment system against which this kind of an approach is measured.

Regardless, standardization alone has to improve margins because of the time saved. The greatest impact would be felt with a multiplicity of guidelines analyzed and applied in this way. To do this for high volume, high cost services probably makes the most sense. Payment alone, however, is not the only positive outcome that could emerge from applying the unified field theory. Other relationships can be bolstered and enhanced to further quality by using the five principles and the theory.

VII. Physicians and Hospitals

Hospitals are struggling to find ways to help their medical staffs so that the physicians will bond with them and utilize their services. From economic credentialing policies[88] to gainsharing programs[89] to straight practice subsidies,[90] hospitals are looking for ways in which they can benefit their physicians and, therefore, be seen as highly valuable by the physicians. Unfortunately, few of these efforts reflect quality driven approaches and many continue to waste physician time. This unified field theory provides another vehicle for hospitals to help physicians help themselves. In the Stark regulations, there is a little appreciated provision that states that a hospital may provide "compliance training" to a physician or the physician's immediate family member who practices in the hospital's local community or service area.[91] For these purposes, "compliance training" is training regarding

> the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).[92]

To help physicians use CPGs in the way described here is completely consistent with the compliance training goals of the Stark regulation. It would train physicians to practice far better billing, coding, reasonable and necessary services documenting, and clinically appropriate referring. Moreover, the programmatic integration of the quality functions and the compliance functions within the hospital, as well as in a large group practice, would also benefit both activities enormously.[93]

Many hospital medical staffs are mired in internecine turf battles, struggles over cross-departmental privileges, and use of ancillary personnel. To bring to bear CPGs in those situations would change the way medical staffs conduct their business.[94] Utilizing these principles within hospitals to change internal hospital practices would also provide an overarching principle of operation for both the physicians and the hospital.[95]

These five principles and theory can drive many other hospital activities, including, but not limited to: (1) the purchase or development of information systems that truly reflect what is necessary to enhance the application of science and the improvement of time and touch between doctors and patients within the hospital;

(2) the flow within the hospital to make sure the right patient is in the right bed at the right time; (3) the manpower personnel planning in terms of hiring those combinations of clinicians necessary to treat particular kinds of patients; (4) the budgeting; and even (5) the strategy and capital management.

VIII. Physicians and Plans

Given the backlash from managed care reform, there is no question that MCOs are struggling with an image problem. They have not yet found a way to sufficiently bond with their physicians in order to regain the credibility lost in the managed care reform struggles. Were plans to implement these five principles and the theory on a collaborative basis with physicians, they would improve their ability to actually "brand" for quality. One can easily imagine the marketing of such a plan: "We pay your physician to treat you with the best available science and to spend time with you." The approach enhances efficiency without sacrificing care purely in the interest of saving money. This kind of approach, particularly when brought to bear in new payment formulas, can begin to really call the question of cost cutting. For physicians to say to the managed care plan, "we will treat our patients in accordance with this guideline, but you will pay us a fair, negotiated rate that reflects our real costs to treat each patient with this condition" truly begins to focus a beam on what the managed care plan is willing to pay for in its "medical loss ratio"—the percent of premium dollars spent on actual care.

In terms of negotiating with plans, the description of the unified field theory is beautifully consistent with clinical integration concepts propounded by the Federal Trade Commission (FTC) and the Department of Justice. These concepts were articulated in their publication regarding the opportunity for clinical integration with the promulgation of their safety zones.[96] There has been only one proposed network clinical integration model that has been evaluated and approved by the FTC.[97] The FTC has taken action against physician networks[98] that were not sufficiently integrated, either financially or clinically. The opportunities offered by this theory, including the ability to clinically integrate in ways in which the fee bargain is truly ancillary to the reason to integrate, is self-evident.[99]

IX. Boundaries for the Theory

It should be clearly understood that this proposal is not intended to be applied universally. Rather, it reflects the belief that too much in healthcare in the United States has emerged out of a regulatory

process that drives to the great mediocre middle. It is time to allow those physician groups who are willing to do so, to say, "we can provide care differently; we will provide care differently; we are willing to be evaluated on this basis, but you will treat us differently in terms of your administrative burdens as well as how you pay us." Consequently, at least initially, this proposal is hardly for everyone. The theory will work for well-organized medical groups, virtual groups in independent provider associations, and those physicians who are interested in innovating to a new model.

The payment approach will not work for all conditions. While there may be a wonderfully clear CPG for the treatment of urinary tract infections, no payor will be willing to pay for such care on this basis, nor ought they. The complexity of applying the principles and theory to urinary tract infections, an inexpensive condition to treat, is not worth the undertaking.

Given the administrative cacophony and disorganization that characterizes most physician practices, standardizing to the science as much as possible, even without payment change, is worth achieving because of the lowered expense and improved quality that would result. Moreover, most significantly, standardization will reduce clinically irrelevant time, improving the doctor-patient relationship and adding satisfaction to the encounter for both the physician and the patient. Reduced administrative burden lowers expenses. Thus, to the extent that a reduced burden reflects standardized care, this should be a major focus of physician efforts and a parallel goal of plans and hospitals.

Finally, pilot projects, demonstrations, and small pockets of activity will be a far better way to implement this theory than to try to apply it throughout a practice, a hospital, or anything broader. As my colleague, Dr. Reinertsen, says, it is important to have "small tests of big ideas" to learn from, improve, and share the experience with others.

X. Advantages

The unified field theory described here simplifies and standardizes care in clinical management of patients within the practice. It speaks to physicians in the way they think and gives them back touch time. Without question, because of the explicit documentation approach, it lowers every fraud risk enumerated earlier. This includes all of the varieties of fraud and abuse risks associated with quality as well as false claims liability to the plan, the hospital, and the physician practice. It can be used to create common goals among all of the players, including hospitals, physicians, health

plans, and even employers. It maximizes efficiency without sacrificing quality and provides a new way to price and negotiate. It has the potential to eliminate the intrusive, and burdensome medical management programs of plans, such as prior authorization and concurrent review. With the application of explicitly agreed upon guidelines, there is no longer a need to document medical necessity and keep checking what the physicians are doing, because what is necessary is incorporated in the guideline.

This approach will reduce malpractice claims. It has now been shown definitively that physicians who do not follow CPGs have a six-fold increased risk of being sued in malpractice.[100] This is more than a risk of an adverse event; it is the vastly increased risk of being sued when guidelines are not followed. The implications of this theory go well beyond payment and likely can have more of an impact than has even been anticipated here.

XI. Conclusion

In the current healthcare environment, we hear loud cries for improved quality. Despite the multiple demonstration projects in the Medicare reform legislation and in the expanding P4P programs, which are at best transitional programs with limits already elucidated here, very few other options are on the horizon. Clearly, we need to be doing something different in our payment and delivery systems for substantial quality advancement.

As I have argued here, physicians are at the core of any opportunity to propel quality forward in a significant way and, therefore, must be taken into account directly and without apology. I believe the arguments made here create a business case for quality that uses physicians as a lever, but goes far beyond them. There is not a single way of implementing the theory. Local circumstances will lend themselves to unique programs. Pursuant to this theory, physicians, and those who depend on them for their business, can more easily do the right thing if the system helps to make the right thing to do the easy thing to do. The doctor-patient relationship provides the touchstone upon which true quality can be generated.

> The only progress we make in health care is the progress we make in medicine. In the daily chaos that is the US health care "system," there are but three elements that matter: patients, caregivers, and medical technologies. Everything else is noise.[101]

Endnotes

[1] Galvin Chassin et al., *The Urgent Need to Improve Healthcare Quality*, 280 J.A.M.A. 1000 (1998).

[2] Institute of Medicine, To Err is Human (Linda T. Kohn et al. eds., 1999).

[3] Institute of Medicine, Crossing the Quality Chasm (2001) [hereinafter Crossing the Quality Chasm].

[4] For a brief history of the development of quality policy over the last thirty years, see Alice G. Gosfield, *Contracting for Provider Quality: Then, Now and P4P, in* Health Law Handbook (Alice G. Gosfield ed., 2004 ed.) (forthcoming 2004) [hereinafter *Contracting for Provider Quality*].

[5] The Leapfrog Group, *at* www.leapfroggroup.org (last visited Mar. 25, 2004). The Leapfrog Group is composed of more than 150 public and private organizations that provide healthcare benefits. *Id.* The group proposes solutions to hospital systems to avoid preventable medical mistakes. *Id.*

[6] *See Contracting for Provider Quality*, *supra* note 4.

[7] Ctr. For Medicare and Medicaid Servs., *National Voluntary Hospital Reporting Initiative Fact Sheet* (Feb. 18, 2004), *available at* cms.hhs.gov/quality/hospital/NVHRIFactSheet.pdf (last visited Mar. 25, 2004).

[8] For information on the Doctor's Office Quality (DOQ) Project, see Ctr. for Medicare and Medicaid Servs., *Physician Focused Quality Initiative*, *at* cms.hhs.gov/quality/pfqi.asp (last visited Mar. 25, 2004). *See also* Letter from American College of Physicians & American Society of Internal Medicine, to the Practicing Physicians Advisory Council (Dec. 16, 2002), *available at* cms.hhs.gov/faca/ppac/amastmt.pdf (last visited Mar. 25, 2004).

[9] *See* Ctr. for Medicare and Medicaid Servs, The Premier Hospital Quality Incentive Demonstration: Rewarding Superior Quality Care (Feb. 18, 2004), *at* cms.hhs.gov/quality/hospital/PremierFactSheet.pdf (last visited Mar. 25, 2004) (for hospitals) [hereinafter Premier Hospital Quality Incentive Demonstration]; Ctr. for Medicare and Medicaid Servs., *Physician Group Practice Demonstration*, *at* cms.hhs.gov/healthplans/research/PgPDemo.asp (last visited Mar. 25, 2004) (for physicians);

[10] *E.g.*, 42 U.S.C. §§ 1395b, 1395b-8, 1395cc-3.

[11] *Id.* §§ 1320c to 1320c-12. *See also* Alice G. Gosfield, PSROs: The Law and the Health Consumer (1976).

[12] *See* Alice G. Gosfield et al., *Utilization Management, Quality Assurance and Practice Guidelines*, *in* Health Law Practice Guide 25-1, at 25-29 to 25-55 (1993).

[13] Ctr. for Medicare and Medicaid Servs., *Quality Improvement Organizations*, *at* cms.hhs.gov/qio/ (last visited Mar. 25, 2004).

[14] 42 U.S.C. § 1320c-3(a) (2004).

[15] *See* Ctr. for Medicare and Medicaid Servs., *Quality Improvement Organization—Statement of Work, available at* cms.hhs.gov/qio/2b.pdf (last visited Mar. 25, 2004).

[16] *Crossing the Quality Chasm* states six fundamental aims for the American healthcare system—to be safe, effective, patient-centered, timely, efficient, and equitable. Crossing the Quality Chasm, *supra* note 3, at 5-6. Transparency is part of patient-centered decisions. *Id.* at 8.

[17] *See* Ctr. for Medicare and Medicaid Servs., *Physician Focused Quality Initiative*, *at* cms.hhs.gov/quality/pfqi.asp (last visited Mar. 25, 2004).

[18] 42 U.S.C. § 1320c-5(b) (2004).

[19] *Id.* § 1395dd.

[20] *Id.*

[21] *Id. See* Joy & Young, *EMTALA: Where We Stand Now—Background and Recent Regulatory and Statutory Changes*, *in* Health Law Handbook (Alice G. Gosfield ed., 2004 ed.) (forthcoming 2004).

[22] For a list of currently applicable conditions of participation, see Ctr. for Medicare and Medicaid Servs., *Conditions of Participation & Conditions for Coverage*, *at* cms.hhs.gov/cop/1.asp (last visited Mar. 25, 2004).

[23] 42 U.S.C. § 1395bb (2004).
[24] Mark Taylor, *Hospital on the Block,* Modern Healthcare, Dec. 15, 2003, at 8.
[25] *See generally* Ctr. for Medicare and Medicaid Servs., Medicare Manual System Pub. 100-16 Managed Care, August 1, 2003, *available at* www.cms.hhs.gov/manuals/pm_trans/R29MCM.pdf (last visited Mar. 25, 2004).
[26] 42 U.S.C. §§ 11101-11152 (2004).
[27] *See* David R. Hoffman, *The Federal False Claims Act as a Remedy for Poor Care,* 45-2 USABulletin, Apr. 1997, at 54, *available at* www.usdoj.gov/usao/eousa/foia_reading_room/usab4502.pdf (last visited Mar. 25, 2004).
[28] *See, e.g.,* 42 U.S.C. § 1396r(b)(2)(A) (2004); H. Guy Collier, *Legal Issues in Long Term Care, in* Health Law Handbook 57 (Alice G. Gosfield ed., 1989).
[29] *See* Hoffman, *supra* note 27.
[30] *See* Dan Sanderson, *Hospital Chief May Soon Be Facing Trial,* Traverse City Record Eagle, Jan. 11, 2003, *available at* record-eagle.com/2003/jan/11cheb.htm (last visited Mar. 25, 2004).
[31] 42 U.S.C. § 1320a-7(b)(6)(B) (2004).
[32] *Id.*
[33] *Id.* § 1320a-7a(a)(1)(E).
[34] *Id.* § 1320a-7a(a)(3).
[35] *Id.* § 1320a-7a(b). It is this proscription that led the Office of the Inspector General to reject most gainsharing programs as violating the law. *See* Alice G. Gosfield, *Legal Mandates for Physician Quality: Beyond Risk Management, in* Health Law Handbook 285, 298 (Alice G. Gosfield ed., 2001 ed.); Alice G. Gosfield, *Making Quality Happen: In Search of Legal Weightlessness*, *in* Health Law Handbook 609, 642 (Alice G. Gosfield ed., 2002 ed.) [hereinafter *Making Quality Happen*].
[36] *E.g.*, 42 C.F.R. §§ 1003.100-1003.135 (2004); *id.* § 417.479.
[37] 42 U.S.C. § 1395nn (2004).
[38] *Id.* § 1320a-7b(b).
[39] *See* Dep't of Health and Human Servs., Off. of the Inspector Gen., Office of Inspector General Work Plan, Fiscal Year 2003, *available at* oig.hhs.gov/reading/workplan/2003/Work%20Plan%202003.pdf (last visited Mar. 25, 2004); Dep't of Health and Human Servs., Off. of the Inspector Gen., Office of Inspector General Work Plan, Fiscal Year 2004, *available at* oig.hhs.gov/publications/docs/workplan/2004/Work%20Plan%202004.pdf (last visited Mar. 25, 2004); Alice G. Gosfield, *The Quality Compliance Nexus: Moving to Programmatic Integration,* 15 AGG Notes at 3, July 2003, *available at* gosfield.com/notes/index.html (last visited Mar. 25, 2004) [hereinafter *The Quality Compliance Nexus*].
[40] *See* Robert L. Roth, *The Little Red Hen Syndrome: States and "Anti-Managed Care Laws," in* Guide to Key Legal Issues In Managed Care Quality, 133, 133 (Alice G. Gosfield ed., 1996).
[41] Arizona, Pennsylvania, Tennessee, and Wisconsin were early data mandating states. *See* U.S. General Accounting Office, Report to Ranking Minority Member, Committee on Commerce, House of Representatives, Medicaid Managed Care: Challenge of Holding Plans Accountable Requires Greater State Effort, GAO/HEHS-97-86, at 2 (May 1997); Alice G. Gosfield, *Health Care Report Cards: Quality in the Public's Cross Hairs, in* Health Law Handbook 501, 533 (Alice G. Gosfield ed., 2000 ed.).
[42] *See* Timothy Jost & Sharon Davies, Medicare and Medicaid Fraud and Abuse 251-64 (2002-2003 ed.).
[43] *See* Alice G. Gosfield, *Quality and Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations* at 11, *available at* www.ama-assn.org/ama1/pub/upload/mm/21/quality_culture.pdf (last visited Mar. 25, 2004).
[44] James L. Reinertsen, M.D., *Health Care: Past, Present and Future,* Group Prac. J., Mar./Apr. 1997, at 38.
[45] Jordan J. Cohen, M.D., *Remembering the Real Questions,* 128 Annals of Internal Med. 563 (1998).
[46] Reinertsen, *supra* note 44.

[47] Crossing the Quality Chasm, *supra* note 3, at 72.

[48] Some of these hazards were elucidated at a meeting on Mar. 28, 2003, of thirty-five chief executive officers and chief medical officers of leading healthcare organizations around the country. Their reactions, observations, and comments informed an overall consideration for improving the business case for quality, which is set forth in Alice G. Gosfield & James L. Reinertsen, M.D., *Doing Well By Doing Good: Improving the Business Case for Quality, available at* uft-a.com/PDF/uft-a_White_Paper_060103.PDF (last visited Mar. 25, 2004).

[49] *See* Ctr. for Medicare and Medicaid Servs., Carriers Manual Pt. 3, Ch. 4 Claims Review and Adjudication Procedures § 4450, *available at* cms.hhs.gov/manuals/14_car/3b4360.asp? (last visited Mar. 25, 2004).

[50] *See* U.S. Dep't of Health and Human Servs., Health Care Financing Administration, Program Memorandum Carriers, *Transmittal No. B-00-24* (May 2000), *available at* cms.hhs.gov/manuals/pm_trans/B002460.pdf (last visited Mar. 25, 2004); Ctr. for Medicare and Medicaid Servs., Certificates of Medical Necessity, *available at* cms.hhs.gov/providers/mr/cmn.asp? (last visited Mar. 25, 2004) (for OMB-approved CMNs for durable medical equipment).

[51] *See* Yuhong Qian, *Bureaucratic Malpractice?: Physicians Push Medicare to Reduce Paperwork, in* NYU School of Journalism, The Bus. of Health (May 1, 2001), *available at* journalism.nyu.edu/pubzone/boh/qian.htm (last visited Mar. 25, 2004).

[52] Marsha Gold et al., Physician Payment Review Commission, Arrangements Between Managed Cares and Physicians: Results from a 1994 Survey of Managed Care Plans 120-28 (February 7, 1995). A revised and shortened version of the same study can be found at Marsha Gold et al., *A National Survey of the Arrangements Managed Care Plans Make with Physicians,* 333 New Eng. J. Med. 1678, 1681 (1995).

[53] Nat'l Comm. for Quality Assurance, *COV Certification Information, at* www.ncqa.org/Programs/Accreditation/Certification/cvo/cvotext.htm (last visited Mar. 25, 2004).

[54] *See* Alice G. Gosfield, *Disease Management, Demand Management and Telemedicine: The Leading Edge of Managing Care, in* Health Law Handbook 235, 240 (Alice G. Gosfield ed., 1998 ed.).

[55] *See* Mark R. Chassin, *Is Health Care Ready for Six Sigma Quality?,* 76 Milbank Q. 565, 574 (1998).

[56] *See* James L. Reinertsen, M.D., *quoted in Loose Lips,* HealthLeaders, Jan. 2002, *at* www.healthleaders.com/magazine/2002/jan/looselips.php (last visited Mar. 25, 2004); James L. Reinertsen, M.D., *Zen and the Art of Physician Autonomy Maintenance*, 138 Annals of Internal Med. 992 (2003) [hereinafter *Zen and the Art*].

[57] *See* Alice G. Gosfield, *Whither Medical Staffs?: Rethinking the Role of the Staff in the New Quality Era,* Health Law Handbook 141 (Alice G. Gosfield ed., 2003 ed.) [hereinafter *Whither Medical Staffs?*].

[58] Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II,* 324 New Eng. J. Med. 377 (1990) (finding that physicians have three-fold exaggerated perceptions of the real risk of being sued for malpractice).

[59] *See, e.g.,* Andy D. Bennett, *State Constitutional Issues Arising From Tort Reform*, 40 Tenn. B.J. 27, 28 (Feb. 2004).

[60] Anderson v. Humana, Inc., 24 F.3d 889 (7th Cir. 1994).

[61] For a broader review of a range of financial incentives and their interrelationship with contractual provisions, see *Contracting for Provider Quality*, *supra* note 4.

[62] For a more comprehensive review of the current iterations of P4P and their implications, see *id.*

[63] Bridges to Excellence, *Diabetes Care Link, at* bridgestoexcellence.org/bte/diabetescarelink/gty_physicians.htm (last visited Mar. 25, 2004).

[64] Premier Hospital Quality Incentive Demonstration, *supra* note 9.

[65] Central Florida Health Care Coalition, *at* cfhcc.com/ (last visited Mar. 25, 2004).

[66] Ctr. for Medicare and Medicaid Servs., *Physician Focused Quality Initiative*, *at* cms.hhs.gov/quality/pfqi.asp (last visited Mar. 25, 2004). Currently the program is being challenged by the Robert Wood Johnson University Hospital and others who are concerned that physicians with admitting privileges at both plaintiffs' hospitals and hospitals participating in the demonstration program will choose to admit to the latter to benefit from the "gainsharing." *Three New Jersey Hospitals Sue CMS To Stop Cost-Cutting Demonstration Program,* HEALTH CARE DAILY REP. (BNA) No.9, at 24 (Feb. 6, 2004).

[67] Bridges to Excellence, *supra* note 63.

[68] Elizabeth A. McGlynn et al, *The Quality of Healthcare Delivered to Adults in the United States,* 548 NEW ENG. J. MED. 2635, 2641 (2003).

[69] *See* Phyllis Maguire, *As They Struggle to Improve Quality HMOs Try a New Incentive: Bonuses,* AM. COLL. OF PHYSICIANS OBSERVER, June 2001, *at* www.acponline.org/journal/news/jun01/bonuses.htm (last visited Mar. 25, 2004).

[70] For the first publication of these principles, see Gosfield & Reinertsen, *supra* note 48.

[71] *See* James L. Reinertsen, M.D., *Physicians as Leaders in the Improvement of the Health Care System,* 128 ANNALS OF INTERNAL MED. 833, 835 & 837 (1998); *Zen and the Art, supra* note 56, at 993; James L. Reinertsen, M.D., *It's About Time: What CEOs and Boards Can Do For Doctors, Nurses and Other Healthcare Professionals*, 2 DISEASE MANAGEMENT & QUALITY IMPROVEMENT REPORT 1 (Apr. 2002), *available at* gosfield.com/PDF/leadarticle.pdf (last visited Mar. 25, 2004) [hereinafter *It's About Time*].

[72] *Minnesota Health Plans and Physicians Create a National "Minnesota Model" for Improving Health Care*, HEALTH PARTNERS, Mar. 13, 2001, *available at* www.healthpartners.com/Menu/0,,5672,00.html (last visited Mar. 25, 2004).

[73] Integrated Healthcare Association, *Pay for Performance*, *at* iha.org/Ihaproj.htm (last visited Mar. 25, 2004).

[74] Tyler Chin, *Doctors Pull Plug on Paperless System,* AM. MED. NEWS, Feb. 17, 2003, at 1, *available at* www.ama-assn.org/amednews/2003/02/17/bil20217.htm (last visited Mar. 25, 2004).

[75] *See It's About Time*, *supra* note 71. For principles concerning how to involve physicians more effectively in hospital and health plan decisions that affect quality, see *Contracting for Provider Quality*, *supra* note 4.

[76] CROSSING THE QUALITY CHASM, *supra* note 3, at 6.

[77] A REPORT ON THE 2003 NEW ENGLAND REGIONAL CONFERENCE, CHRONIC ILLNESS AND HEALTH CARE PAYMENT: A SPRINGBOARD TO SUSTAINABLE CHANGE at 1 (May 13, 2003), *available at* uft-a.com/PDF/FinalReport.PDF (last visited Mar. 25, 2004).

[78] The primary beneficiaries of system savings, however, were CMS and employers , not physicians or hospitals. JACK HOMER ET AL., MODELS FOR COLLABORATION: HOW SYSTEM DYNAMICS HELPED A COMMUNITY ORGANIZE COST-EFFECTIVE CARE FOR CHRONIC ILLNESS 31-32, *available at* www.wwpp.org/static/gems/wwppDiscuss/sdp.pdf (last visited Mar. 25, 2004).

[79] *See* Maguire, *supra* note 69.

[80] *See* INSTITUTE OF MEDICINE, GUIDELINES FOR CLINICAL PRACTICE 25 (Marilyn Field & Kathleen Lohr eds., 1992) [hereinafter GUIDELINES FOR CLINICAL PRACTICE]; CROSSING THE QUALITY CHASM, *supra* note 3, at 151-52; Chassin, *supra* note 55.

[81] *See* GUIDELINES FOR CLINICAL PRACTICE, *supra* note 80, at 26.

[82] *See* Alice G. Gosfield, *Gosfield's Unified Field Theory of Health Care Management*, 11 AGG NOTES, Mar. 1999, *available at* gosfield.com/notes/index.html (last visited Mar. 2, 2004), *reprinted in* Alice G. Gosfield, *Integrating Clinical Guidelines to Administration Process Can Lower Risk*, 1 J. HEALTH CARE COMPLIANCE 9 (1999).

[83] INSTITUTE OF MEDICINE, GUIDELINES FOR CLINICAL PRACTICE: DIRECTIONS FOR A NEW PROGRAM (Marilyn Field & Kathleen Lohr eds., 1990).

[84] National Guideline Clearinghouse, *at* www.guideline.gov/ (last visited Mar. 25, 2004).

[85] *See, e.g.,* Institute For Clinical Systems Improvement, *Diagnosis and Management of Asthma, available at* www.icsi.org/display_file.asp?FileID=1189 (last visited Mar. 25, 2004) [hereinafter *Asthma*]; Institute For Clinical Systems Improvement, *Diagnosis and Management of Infertility, available at* www.icsi.org/display_file.asp?FileId=153&title=Diagnosis and Management of Infertility (last visited Mar. 25, 2004).

[86] For a brief consideration of how this might play itself out in practical terms, *see* Gosfield & Reinertsen, *supra* note 48, at 21.

[87] *Diagnosis and Management of Asthma*, *supra* note 85.

[88] *See* Letter from Alice G. Gosfield, to the Dep't of Health and Human Servs., Off. of the Inspector Gen. (Jan. 17, 2003), *available at* www.gosfield.com/PDF/oigv2.pdf (last visited Mar. 25, 2004).

[89] *See Making Quality Happen*, *supra* note 35, at 639.

[90] Debbie Johnstone, Address at the American Health Lawyers Association meeting (Feb. 12, 2004).

[91] 42 C.F.R. § 411.357(o) (2004).

[92] *Id.*

[93] *See The Quality Compliance Nexus*, *supra* note 39, at 7.

[94] *See* Alice G. Gosfield, *The Organized Medical Staff: Should Anyone Care Anymore?,* 15 AGG Notes, at 7, Feb., 2003, *available at* gosfield.com/notes/index.html (last visited Mar. 25, 2004); Alice G. Gosfield*, Whither Medical Staffs?, supra* note 57. For a presentation on how relationships between hospital boards, administration, and medical staffs might be changed even more radically to improve quality, see Alice G. Gosfield & James Reinertsen, M.D., *Medical Staff, Board and Administration: Where the Rubber Hits the Road in the Quest for Quality* (June 14, 2003), *at* www.gosfield.com/PPT/AMA-OMSS.052903.fnl.ppt (last visited Mar. 25, 2004).

[95] *See It's About Time, supra* note 71.

[96] Jeannine Mjoseth, *DOJ, FTC Issue Revised Health Care Antitrust Enforcement Policy*, 5 Health L. Rep. (BNA), Aug. 29, 1996, at 1309.

[97] U.S. Fed. Trade Comm'n., *Staff Advisory Opinion: MedSouth, Inc.*, (Feb. 19, 2002), *available at* www.ftc.gov/bc/adops/medsouth.htm (last visited Mar. 25, 2004).

[98] *See* settlements in Piedmont Health Alliance Inc. [File No. 0210119]; Tenet Healthcare Corp and Frye Regional Medical Center [File No. 0210119], Southwest Physicians [File No. 0110197], Washington University Physicians Network [File No. 0210188], Physician Network Consulting and Baton Rough Orthopaedic Services, et al [File No. 021078], Maine Health Alliance [File No. 0210017] and Brown and Toland [File No. 9306] (which remains unsettled at this writing). All settlements and action notices *available* at www.ftc.gov/os/adjpro/ (last visited Mar. 25, 2004).

[99] For a useful and insightful analysis of the boundaries of clinical integration, *see* Robert Leibenluft, *Clinical Integration: Assessing the Antitrust Issues*, *in* Health Law Handbook (Alice G. Gosfield ed., 2004 ed.) (forthcoming 2004).

[100] Scott B. Ransom et al., *Reduced Medicolegal Risk by Compliance with Obstetric Clinical Pathways: A Case- Control Study,* 101 Obstetrics and Gynecology 751, 753 (2003).

[101] J.D. Kleinke, Oxymorons 354 (2001).