TOTAL QUALITY MANAGEMENT AND THE SILENT PATIENT

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Abstract This essay examines the impact of the imposition of businesses techniques, in particular, those associated with Total Quality Management, on the relationships of important components of the health care delivery system, including payers, managed care organizations, institutional and individual providers, enrollees, and patients. It examines structural anomalies within the delivery system and concludes that the use of Total Quality Management techniques within the health care system cannot prevent the shift of attention of other components away from the enrollee and the patient, and may even contribute to it It speculates that the organization ethics process may serve as a quality control mechanism to prevent this shift and so help eliminate some of the ethically problematic processes and outcomes within the health care delivery system

1. Introduction

The health care system in the United States has undergone radical changes in the last two decades. Many elements of this complex system are in transition, including the locus of decision making, the objectives or goals of the system, and to some extent, even the ordering of its priorities. Some of these changes have confused and angered many health professionals, as well as a large proportion of the general public.[1,2,3] Health care has always been a business, and has been acknowledged to be such; but with recent moves to a more integrated system and with the addition of new players in various forms of managed care organizations (MCOs), the model of what kind of business health care is has undergone a transformation as well.

At mid-twentieth-century, medicine was primarily in the hands of an alliance of professionals whose business model resembled that of the small businessman. Physicians established relationships with individuals seeking medical care, and mediated their relations with hospitals, pharmaceuticals, medical technologies, and other professional groups. Now, provision of health care is less like an independent small business and more like big business, with integration of producers and suppliers, increased emphasis on volume and efficiency, and the introduction of different business strategies. But some of the preconditions for the

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success of newer business strategies are lacking in the area of medicine, leading to confusion and widespread dissatisfaction. In this paper we focus quite specifically on the structural presumptions of one well-established and demonstrably effective industrial business strategy[4]—Total Quality Management (TQM)—and explore reasons for its relatively modest successes in health care, despite persistent and widespread efforts to implement it.

From the standpoint of forces working for health care reform in the early 1990s, the quality of the medical care available in the health care system of the United States was unproblematic, but the cost of health care to the society was deemed excessive. It was the cost of health care that was the focus of attention, and it was high and increasing. Discussion at that time focused on overutilization, waste and inefficiency, as well as on troubling questions of access, which has since then virtually disappeared from the discussion. As a result of the shift in the subsequent decade from a professional to a market model, managed care has become the dominant model for health care delivery in the United States,[5] challenging, and to a large extent replacing, the model of the freestanding individual physician. In order to be a responsible, effective, and profitable component of the health care system, a managed care organization must deliver to those populations for which it is paid to be responsible a high quality of health care for a reasonable cost.[6,7,8,9] Thus, the MCO has assumed the obligation to balance cost and quality in the delivery of care.

As part of the reaction to escalating health care costs, cost management by some MCOs has proceeded on the assumption, widely accepted by the industrial business community, that constant or incremental improvement in the processes of production could contribute significantly to controlling health care costs without a reduction in the quality of the health care delivered to individuals. Toward this end, MCOs have applied some mechanisms associated with businesses in other areas of the economy to health care. We examine the relationships between several components of the health care delivery system and look at the effects of these mechanisms on the contemporary system.

The components of the health care delivery system that we are most concerned with are the payers for health care products and plans (employers and the government, which is also a payer of health care plans through its role as an employer and through programs like Medicare and Medicaid), the MCO, individual health care providers, health care organizations (HCOs), and the enrollee/patient. We map the mechanisms associated with TQM on these components and view the results from the perspective of the enrollees (some subset of whom are patients), and from the perspective of the individual patient. We conclude that because of some structural anomalies of the health care system, the use of TQM techniques within the health care system cannot prevent the shift of attention of other components away from the enrollee and the patient, and may even contribute to it. If quality mostly turns out to be quality based on payer priorities, rather than quality according to patient criteria, to an unacceptable extent, the voice of the enrollee/patient vanishes from the formulation of quality in

the health care delivery system. Further, if business mechanisms interfere with provider judgment, they interfere with patient trust, with provider morale, and with the implicit rationale of medical practice. Business practices that are justified on the ethical premises of MCOs can have seriously negative ethical implications for other components of the system of which they have become a part, components with different responsibilities.

The MCO is responsible to the larger society, for which it has undertaken to constrain costs, but also to the patient for whom care is delivered, and to the providers being reimbursed for delivering that care. The obligations to the providers are direct and contractual. The obligations to the patients are indirect, but no less important from the standpoint of the health care system as a whole. If its role as intermediary between the payers and the providers of health care cannot adequately take into consideration the quality of the care delivered to patients, then this is a serious problem for the MCO. If it is true that the implementation of business mechanisms forces attention away from the patient, it becomes important to introduce strategies and mechanisms that encourage the system to reconsider the expectations of the enrollee/patient within a new paradigm. We conclude this essay with a discussion of health care organization ethics and its potential to address this challenge.

2. *Total Quality Management*

A key assumption of modern industries is that by improving efficiency, cost savings can be made without sacrificing quality. This argument uses a business strategy made popular by W. Deming called "Total Quality Management."[10] The idea of TQM and associated continuous quality improvement and quality control mechanisms swept through corporate America in the early and mid-1980s. TQM and its associated techniques were wholeheartedly adapted by industries still reeling from the sharp recession of the early 1980s and endeavoring to find sustainable competitive advantages.

The idea behind Total Quality Management and its associated technique, Continuous Quality Improvement (CQI), is conceptually simple. If producers critically examine their processes of manufacturing or service they can find ways of incrementally improving them. Some of these improvements could occur by eliminating duplicate or wasteful processes. Identifying and eliminating processing mistakes as early as possible improves processes, as does focusing on the raw materials used in production to weed out unacceptable material before it enters the production stream. Improvements could be made by eliminating variations in the production of goods and services. These techniques require standards (benchmarks) of quality if they are to be used, so that defects, redundancy, and variability can be identified and so eliminated. It is worth noting that these techniques were not designed to be flexible in their implementation. On the contrary—it is their rigidity that has made them so effective in industries using repetitive or automated processes like the electronic, automotive, and banking industries.[11]

The goal of these techniques is to improve the production processes. But in the traditional market model, and thus in the TQM model, it is the customer who is the final arbiter of the quality of the product, and it is the expectations the customer has about the product that the producer is trying to meet or exceed.[12] The decision of a customer to purchase a product is based on her expectations of it. These expectations will always be some function of the price of the product. Thus, perceived quality is achieved when the expectations the customer has about a particular product are either met or surpassed. If the producer is able to improve production processes, and still produce a product of similar grade or conformance to the same standards, savings are generated. These savings can be passed along to the customer by either lowering the price or improving its grade. Customer expectations of the quality of the product or service are met or surpassed because either a lower price is associated with the same product, or a better product is associated with the same price. The market can accommodate to, and reflect fairly, variations in the grade or conformance of the product when the customer of the product is also the payer for that product. In short, in the TQM model, producers determine the grade of or conformance to standards of a product, but quality is determined by the expectations of customers for that product. Producers try to satisfy these expectations in order to keep customers loyal and to increase market share. These expectations are a function of past experience or future expectations, but when acted on by informed customers with control over their purchases, these expectations can be reflected in the price of the product.

TQM and CQI have been given credit for improving the efficiency and effectiveness of a variety of businesses in a number of economic sectors. When market model business strategies began to have an impact upon health care delivery in the last decades of the twentieth century with the introduction of managed care, some theorists and policy makers began to look to TQM/CQI as another possible strategy for the health care industry. Because of its focus on quality as well as cost, it was hoped that the introduction of TQM could minimize the impact of cost containment on quality of care.

TQM and the New Health Care Industry

Even before the current wide acceptance of a market model for health care delivery in the United States, a number of physician/executives (such as Batalden, Berwick, and Blumenthal) had been exposed to the idea of TQM by attending seminars offered by W. Edwards Deming in the mid- to late 1980s, and had seen its possibilities for improving the quality of health care. As the managed care revolution took hold, some of those individuals were in a position to influence important oversight agencies to emphasize quality of care. Some became leaders within such accrediting agencies as the Joint Commission of Accreditation of Healthcare Organizations and the National Committee on Quality Assurance, and were influential in incorporating the substance of the message of CQI into the accrediting approach of such organizations.[13]

The Joint Commission of Accreditation of Healthcare Organizations (JCAHO) evaluates and accredits more than 19,000 health care organizations in the United States, including hospitals, health care networks, managed care organizations, and health care organizations that provide home care, long-term care, behavioral health care, laboratory, and ambulatory care services. Accreditation from the Joint Commission is required for Medicare and Medicaid reimbursement. Not surprisingly, therefore, most health care organizations and many managed care organizations are accredited by JCAHO. The Commission adopted the theory of Continuous Quality Improvement in the late 1980s and early 1990s, and has worked since that time to align its accrediting process with CQI theory and practice.[14] In 1992, JCAHO introduced a requirement that those organizations it accredits show visible evidence of commitment to improving quality of health care through continuous quality improvement programs.[15,16,17]

Efforts have also been made to introduce TQM to managed care organizations. The National Committee on Quality Assurance (NCQA) is an independent, non-profit organization whose mission is to evaluate and report on the quality of the nation's managed care organizations so that purchasers of managed care products, particularly large employers, can make more informed choices about the plans they purchase. The HEDIS dataset developed by NCQA is an attempt to encourage employers to use quality of care as a criterion in purchasing—that is, to have and apply data that correlates the cost of a plan with its quality.[18] NCQA reports that more than three-quarters of Americans enrolled in HMOs are in plans that have been reviewed by NCQA.[19] NCQA sees the promotion of quality improvement as an integral part of its mission—a managed care organization will not be accredited by the NCQA without a commitment to quality improvement.[20] Because employers played a vital role in creating NCQA and some similar organizations, it is possible that the TQM influence resulted as much from the experience of these companies with TQM in their own workplaces as from any understanding of how it could be applied in health care.[21]

Despite the efforts of industry leaders, there seems to be a wide consensus that TQM has not achieved the results envisioned by its early advocates.[22] Various explanations have been offered, including physician resistance to the approach and persistence of more traditional management approaches.[23] We suggest, however, that insufficient attention has been paid to the structural anomalies of the health care market that make the application of TQM approaches counterproductive, producing ethical tensions in the system that offset some of the advantages which might be expected to accrue from the approach, and in some cases introducing conflicts which stand in the way of quality improvement.

There is an important anomaly in applying TQM to the health care delivery system. Theories of TQM assume that the payer, the customer, and the consumer are identical. In the context of traditional businesses in which TQM arose, it is the customer who is the final arbitrator of the quality of the product, and the customer is both the payer and the consumer. A customer chooses to purchase a

product based on her expectations about it and what her priorities are for it. The customer has the option of prioritizing either quality or cost. Customers demonstrate their preferences by making choices between products.

To our knowledge, TQM theory does *not* address the difficulties of satisfying the expectations of two different customer sets with the same product. Within a TQM model, the customer is identified and profiled so that customer expectations are known. The producer knows that differing expectations among customers signals the need for different products—that trying to satisfy the differing expectations of two customers through a single offering that purports to satisfy the expectations of both is usually a recipe for disaster. But in health care in the United States, the payer is not the consumer.[24] The payer and the patient/enrollee, the actual or potential consumer of the health care delivered, are distinct groups of MCO stakeholders. Since they are different, they will have different, possibly even incompatible, expectations about the standards to which the health care services that the MCO has agreed to deliver are expected to conform.

TQM and the MCO

The term "managed care" covers a variety of different models, ranging from plans like Kaiser Permanente, with a long history of delivering care via proprietary facilities and salaried physicians, to plans that "manage" administrative details alone, subcontracting with providers to actually provide treatments. For our purposes we are concentrating on the latter model. MCOs provide health care insurance and arrange for the delivery of a broad range of integrated health care services for populations of plan enrollees, financing the services prospectively from a predicted, limited budget with the goal of delivering cost-efficient and high-quality care.[25] The MCO, as we are using the term, contracts with payers, primarily large employers including the government, and in return for a pre-set fee, promises to deliver to the population of plan enrollees for whom payers are responsible a certain set of health care products or services.

If we apply the framework of the TQM model, the MCO structurally occupies the role of the producer of health care services. It is the MCO who promises the delivery of a certain set of health care services, and does so by choosing, and contracting with, health care providers and other suppliers of health care products to make good on that promise. If the MCO is the *producer* of health care services, the health care provider is a *supplier* of the MCO. Producers in the TQM model insist that their suppliers meet certain standards. This avoids potential defects in the production process later on. In the same way, the MCO may insist that its individual health care providers meet certain standards of knowledge, skill, and judgment in the provision of health care services and that its institutions possess a certain level of certification. As producer, the MCO, applying techniques associated with TQM, initiates various strategies to eliminate waste, redundancy, and variability in the health care delivery system.[26] These strategies aim at producing efficiencies and cost savings without sacrificing quality. They include consolidating services, eliminating excess capacity

and duplicated services, and consolidating purchasing and distribution. Another important objective is control of clinical variability.[27] Standards are needed to control variability. If maintaining or improving the health status of their enrollees is the service for which managed care contracts, variability in health interventions is a "production" problem that needs to be addressed. The MCO undertakes to accumulate comparative, cumulative, and longitudinal data by gathering information across delivery sites to track alternative treatments, resource use and clinical outcomes. The data gathered can contribute to refining treatment protocols. Ideally, uniform data allows for comparisons, and standards can be chosen for variability control in achieving desired outcomes and so support the promise of the MCO as a device for the continuous and systematic improvement in the processes of care.[28, 29]

But techniques associated with TQM in other industries have led to some attempts to control suppliers that are ethically and practically problematic in the context of health care. Control of clinical variability by the producer, that is, the MCO, rather than on the level of the supplier, the provider of medical services, has often proved counterproductive. Attempts on the part of the MCO to impose their choice of practice guidelines, treatment plans, and similar variance controls on providers have not been free of conceptual and practical problems. Medical outcomes are difficult to quantify in some respects. Medical practice is as much an art as a science, and in any given medical situation there are likely to be a number of variables that determine the appropriate treatment. So the usefulness of protocols, practice guidelines, and plans of care may vary across medical specialty areas and different diagnoses. Variance control mechanisms are most useful when they guide and inform individual caregivers, while they can be disastrous when they are too rigid or inflexible to accommodate excellent provider judgment. Certainly, rigidity and inflexibility in their implementation helps explain provider distrust with guidelines written by so-called national experts.[30] Perhaps the most notorious example of producer-level variance control was the attempt to limit reimbursement of in-hospital stays of new mothers to 24 hours—a policy that eventually led to the passage of the Newborns and Mothers Health Protection Act of 1996.[31] One observer, in an article espousing the idea that good medicine is good business, writes:

> Clinical discretion is crucial if physicians are to be able to negotiate with their patients to reach mutually acceptable treatment regimens. If the physician has little leeway to offer the interventions that would best fit the patient's personal values, comfort, and circumstances, then in an important sense, they do not have a relationship with each other. Rather, they relate to the intermediary who tells each of them what to do. Furthermore, if the physician has not authority to negotiate reasonable solutions with the patient, trust is difficult to develop. Without trust, the patient may not only be reluctant to agree to the services he is offered, he may also be suspicious on occasions when the physician suggests an intervention is necessary.[32]

Good medicine may be good business, but such misapplications of good business models to an inappropriate context suggest that good business is not necessarily good medicine.

Who Is the Customer of the MCO?

In the traditional industries in which TQM has been successfully applied, the consumer and the payer are identical, and customer power is demonstrated by the ability to make choices and exit any service relationship deemed unsatisfactory. We have suggested that in order to operate as an ethically responsible component of the health care system, the MCO must balance cost and quality. Groups occupying different roles in the health care system have differing perspectives on what counts as quality, and different criteria for the standards that the care is expected to meet. If different groups have different expectations, this bifurcation of the customer set can be expected to create problems for an MCO attempting to implement TQM to improve its market position. In the anomalous structure of health care, who is the true customer of the MCO?

a. The Enrollee. Is the MCO trying to meet the expectations of its enrollees? Enrollees expect to be charged a reasonable amount for their health plan when well, and to receive good quality of care when ill. The obligations of the MCO to the enrollee are indirect—mediated through the payer, with whom the conditions of plans to be offered are directly negotiated. The priorities of the enrollee divide situationally between cost and quality. When well, the enrollee, like the payer, may prioritize cost, but when ill, may be much more critical of elements of quality that may be invisible to someone not actually receiving health care services, and may prioritize quality—and quantity—of coverage. This structural bifurcation of the enrollee into well subscriber and patient utilizer constitutes an additional complication for the conscientious MCO. Both the enrollee and the sponsoring payer contribute to the cost of membership in a given health plan. So both are in some sense customers of the MCO, although customers in different situations. One customer, the payer, has a wider degree of choice than the other customer, the enrollee. It is the employer or sponsoring government agency that decides what range of choice of plans will be available to the subscribers they sponsor.

Many of the characteristics measured by satisfaction surveys are as little under the control of the MCO as of the enrollee. Health care plans, for the large majority of Americans, are available through their employer. As we shall see, questions of range of choice and variety of coverage are evidenced by numerous surveys to be important to the subscribers to health plans, but are limited by the options offered by the payer.

Save for the desire for choice and consistency of coverage, it is difficult to assign fixed expectations to disparate enrollee groups in disparate organizations—and then try to evaluate overall satisfaction levels. Large organizations are more inclined to view their employees as long-term resources and so may

take a different approach to purchasing insurance than smaller organizations.[33] Enrollee expectations may vary depending on certain demographic characteristics—especially level of income. Studies have shown that the upper-income enrollee expects (and receives) a more comprehensive and flexible health care plan than the lower-income employee of the same firm.[34] Since not all employees have a choice about their health plan, enrollment itself cannot be read as endorsement of that plan if it is the only option available. If enrollees are not well-informed or well-educated about the options involved in plans, they will often allow their benefits managers to make those decisions for them,[35] but satisfaction studies cannot serve as proxies for expectations in the context of a poorly informed population. The benefits available to all employees of a given firm may be based on the preferences of a minority of the employees, often those with higher salaries.[36, 37]

Enrollees' expectations, then, are bifurcated by their situation, which alter the order of their priorities. Their main method of expressing their satisfaction is choice and exit—the freedom central to the market model of choice of plan and provider. But that choice is limited, to some extent by their sponsors, and to some extent by the MCOs with which their sponsors contract. Limited choice for the enrollee has important consequences. In a managed care environment, the quality of providers and characteristics of the delivery system are important at the time of enrollment. If there is limited or no choice, then the enrollee has no way of showing preferences. The enrollee's voice is effectively silenced.

b. The Payer. Payer expectations of the MCO are both more direct and less ambiguous. They are detailed in the arrangement the payer has with the MCO. The number of plan options available to the enrollee is a cost-related decision by the payer. The range of coverage of those plans is also a payer decision; any employer has the option of seeking out and subsidizing the most expensive and expansive coverage for all employees, but not surprisingly, not all employers choose to do so.

Studies have shown that the expectation of choice of health care plan is important to enrollees.[38, 39] This is because the choice of health care plan determines which provider the enrollee will be associated with as well as the level, amount, and quality of services available to them. These considerations will directly impact continuity of care as well as the quality of care the enrollee receives when the enrollee becomes a patient. But a recent survey of working adults shows that this value is not widely acknowledged by sponsors of their health plans. The 1997, Kaiser/Commonwealth National Health Insurance Survey[40] showed that only 2 out of 5 working adults, ages 18 to 64, are offered two or more plans by their employer. Forty percent of working adults have a choice of only one employer-provided plan—generally a managed care plan. The remaining 17 percent of employees are not offered health insurance at all through their employers. The report also found that 31 percent of workers have changed plans in the last two years; of these, 80 percent changed plans involuntarily. Other observers have

confirmed this evidence. One commentator notes that only a minority of the working-age population effectively control their health care choices. The main group of employees who still enjoy broad choices are those in the public sector, through such programs as the California Public Employees' Retirement System and the Federal Employees Health Benefits Program.[41]

Are enrollees satisfied with this state of affairs? The Kaiser/Commonwealth report concludes that those who are without choices are more dissatisfied with their health plans, the choice of physicians available to them, and the quality of care available to them—especially those enrolled in managed care who have no choice. Specifically, 22 percent of those enrolled in a managed care plan without choice are "somewhat to very dissatisfied" with the plan chosen for them; 18 percent of those enrolled in a managed care plan without choice are "somewhat to very dissatisfied" with the choice of provider offered; and 16 percent of those enrolled in a managed care plan without choice are "somewhat to very dissatisfied" with the care they have received.[42] If customers are identifiable by their powers of choice and exit, it is the payer, not the enrollee, who has this power.

Observers of the health care industry know that limited choice on the part of the enrollee means that market mechanisms cannot force MCO accountability for quality in a plan.[43] In an effort to introduce some measure of responsible purchasing, the NCQA collects data and produces "report cards" that purport to measure the quality of plans and so allow informed choice among buyers of health care plans. But Michael H. Bailit, president of Bailit Health Purchasing in Massachusetts, which assists public agencies, purchasing coalitions, and employers in the purchase of managed care services, has claimed, "Despite the great strides made in quality measurement and reporting, purchasers and consumers seldom buy because of quality of care. Instead, purchasing decisions are based on cost, network size, and administrative convenience."[44] Further, the MCO industry knows this. High quality of care scores win few if any contracts. Health plans will continue to make decisions to trade off quality for cost, and the interests of the public, Bailit suggests, will continue to suffer unless accountability or quality considerations are mandated by federal agencies. As examples, Mr. Bailit points to Fallon Community Health Plan and Harvard Community Health Plan, which were recently marked by *US News and World Report* as the two highest quality MCOs in the United States.[45] These two health plans have watched their competitors experience dramatic enrollment growth while they have lagged behind. As a result they must restructure or else risk bankruptcy.

An industry observer, who believes that the health care is a business and should be run like other industries, writes:

> The managed care industry has developed and installed a pervasive infrastructure of heavy-handed and cumbersome command and control systems that manage cost not care. Window dressing about quality and other marketing claims notwithstanding, the primary goal of such systems has been singular: reduce direct costs associated with medical decision making, regardless of quality, outcomes and even long-run economics.[46]

If purchasers are, as Mr. Bailit claims, more focused on the cost of plans rather than their quality, then the question is whether or not the MCO has responded to this mandate. If it has, then according to the TQM model, we must infer that the payer is the MCO's real customer. If this is true, then the MCO will not consider enrollee expectations or will consider them only secondarily when formulating the product it will offer the payer.

Has the MCO responded to the mandate of cost control by the payer? We believe that it has. We have seen new models of managed care, new pricing structures, and new information technologies as MCOs have sought to restrain the growth in health care costs in order to price their products competitively to gain market share through fulfilling the payer mandate for cost control.[47] And their efforts were at least initially successful. After years of growth, health care's share of the GDP stabilized around 13.6 percent for six consecutive years.[48] The TQM efforts of accrediting agencies such as NCQA, or professional advisors like Bailit Health Purchasing, are designed to make information about some quality considerations of MCOs available to the purchasers of plans, the payers. Their frustration with the relatively low utilization of such information by employers reflects the continuing prioritization of cost over quality by the payers for health plans.

Providers: Suppliers of the MCO

We have seen that the MCO occupies the role of producer in the TQM model. As producer, the MCO controls the grade or the conformance of the health care services it has promised to deliver through use of variance control mechanisms and techniques to improve its processes of production. But the clever producer knows that controlling its own processes of production may not be sufficient to control or reduce costs over the long term. It must also influence his suppliers' processes of production. American business has achieved this by aligning incentives such that the goals of the producer become the goals of the supplier.

The MCO's suppliers include the individual providers and/or health care organizations that contract with the MCO to provide health care interventions for their designated population of enrollees. The efficient MCO, according to the TQM model, will try to control or influence the production processes of its health care suppliers not only by using variance control techniques, but also through the use of incentives. These incentives include payment limits, preauthorization requirements for some services, capitation arrangements, bonuses, withholds, and gatekeeper mechanisms.[49, 50] These arrangements are designed to ensure that the provider bears some of the risk that the actual costs of care may be greater than the anticipated costs of care, and reward the provider for keeping the actual costs of care below anticipated costs. Such incentives can be viewed as a profit-sharing scheme, and work by introducing a conflict of interest in the relationship between the provider-supplier and the individual patients he cares for. They encourage the provider to prioritize efficient utilization of

health care resources across the group of their patients, thus adopting the producer's perspective, rather than prioritizing the treatment of individual patients. The assumption behind these mechanisms is that most persons will respond to well-designed incentives that put income and job security at risk, and since they are effective from the perspective of the MCO they are here to stay, at least for the duration of the managed care revolution.[51]

Who Is the Customer of Health Care Providers?

If the individual provider and institutional providers are, as we have suggested, suppliers of the MCO, then this means that from the standpoint of the providers, the MCO, as the source of their payment, is their customer. Since the MCO is the source of payment for the provider, it is that customer's priorities for the balance of cost and quality, and for the content of the criteria for defining quality, for which the provider is held responsible, and rewarded. But providers have another customer—the patient. The enrollee, we have argued, is only secondarily a customer of the MCO. Does that subset of enrollees actually requiring care—patients—occupy a more central role in the relation between the individual or institutional provider and their customer, the MCO?

The anomaly discussed above of systematic ambiguity of customer recurs on the level of the provider as well. Providers have the same problem with respect to the patient as the MCO has with respect to the enrollee. Providers contract with the MCO to deliver health care services and declare their mission to be excellent patient care. Thus, providers promise to serve two different customers, just as the MCO promises to serve two different customers. The payer (in this case, the MCO) and the recipient of care, the patient, are not identical, so their expectations of providers will be different. If their expectations are different, their experience of the quality of a health care intervention will be different. The group whose expectations are being met is the true customer. We asked earlier who was the primary customer of the MCO, and argued that the MCO acts as if its real customer is the payer—the employer or the government. We need to ask now who is the true customer of health care providers.

a. The Payer. The expectations of the MCO are quite clear. They are reflected in the contractual arrangements the MCO has with a provider. The MCO expects the providers to deliver care to those of their enrollees who are in need of it, to distribute the health care resources entrusted to them effectively and efficiently, and to assume the financial burden of costs of care that exceed the amount guaranteed by their contracts. The perspective of the MCO, and an important criterion for judging quality of care from their perspective, is allocation of resources. Is the resource of health care provision—the product of the MCO—most effectively and efficiently distributed by allocating this treatment to this patient? The cost-benefit calculations that produce answers to these questions are calculations over populations. Many of the incentives to align provider interests with those of the MCO are incentives to adopt this resource perspective.

b. The Patient. The patient expects his/her health care plan to provide good quality care for the price paid as an enrollee. The patients' expectations are set by their experience with an earlier system, and are defined by what counts as an optimum treatment for their individual condition.

The Old Medicine

In the past, patients were structurally and functionally the customers of their providers—even when, as in recent decades, it was frequently a third party that paid the bills. Since the inception of the HCO as a charity institution in the early 1700s through the growth of the health care organization into a large, technologically complex institution, society made available the resources to build and maintain health care organizations, to fund individual medical training, and to fund research. Moreover, society rewarded its individual health care providers and HCOs both monetarily and with a large degree of social power.[52] In return, society asked that its individual providers and HCOs acknowledge and try to meet the needs of its members. Individuals who had need of health care services and products had reason to expect that their care would be technologically advanced and that health care providers could be trusted to deliver these services and products in such a way that would benefit the individual patient. Not only were these agendas in alignment, they were formalized into business structures (the small business model), reimbursement mechanisms (fee-for-service), and codes of ethics for health care providers.[53] Central to the ethics formulations of all providers, institutional and individual, is the primacy of the interest of the patient.

Providers, both individual and institutional, tend to incorporate some form of this claim of the primacy of patient's interests in all their codes. Some form of it is a central feature in the mission and vision statements of health care organizations. It is embedded in statements of patients' rights and responsibilities, and in codes of ethics formulated by professional associations, like the American Medical Association, that seek to inform the behavior of its members. Some of these principles hold providers to high standards—for instance a commitment to excellent care or a commitment to put the interests of the patient before the interests of the provider. Others imply some sort of reciprocity between the patient and the provider, as, for instance, the often-made commitment to joint decision making in statements of patients' rights. The primacy of patients' interests is widely accepted and entrenched within the regulatory system. Academic health care organizations, for instance, must pledge to honor the rules governing research protection for human subjects in order to receive government funding for such research. Institutional ethics—both research ethics (Institutional Review Boards)[54] and patient care ethics (Healthcare Ethics Committees)[55] focused on the areas of interface between the medical establishment and individual patients, in the research protocol or at the bedside where the individual patient was most vulnerable. Since these principles have been endorsed by society, to some extent they are embedded into

expectations of quality society has about the practice of medicine and the relationship of the patient to the institutional or individual provider.

In spite of the argument that fee-for-service encouraged waste, duplication, and unnecessary services,[56] we believe that for most of the twentieth century, the social expectations were realized. The agendas of those involved in the delivery of care were in broad agreement, and *patients considered themselves to be (and were considered by providers to be) the actual customers of providers.* Patients were able to make their preferences for care known and they were free to make choices among providers. These codes of ethics, business structures, reimbursement mechanisms, and institutional protections, reinforced patients' expectations of the quality of health care they would receive within the health care delivery system—that care would be technologically advanced, readily available, and that providers could be trusted to act in their interests.

The New Medicine: Patients or Populations?

An explicit shift in the goals of medicine from care of individuals to efficient allocation of resources represents a transformation of the ethical basis of health care. Traditionally, public health has adopted a population perspective, and explicitly discusses what kind and degree of infringement of individuals' rights is acceptable in aid of the protection and furtherance of the health of the larger collective. But it is exactly this population perspective that has, until recently, differentiated public health from medicine. Insofar as the MCO is the designated social agent of cost containment, the MCO has some justification—indeed, some obligation—to think about resource distribution. But the TQM mechanisms adopted by the MCO to implement their cost-containment agenda threaten to exceed their cost-containment prerogatives, and begin to threaten quality of care—however little this side effect is desired by any of the participants. As MCOs assume control of more and more care decisions, the perspective of resource distribution gains power in health care in general. Providers, especially individual providers, are well aware of the conflict with their historical professional obligations, and a passionate controversy about whether a new ethics is necessary for the new medicine is beginning to appear in the medical literature.[57]

Patients are not interested in patient populations or in the needs of a population and there has been no clear or visible reconciliation between prioritizing the interests of the group over the interests of the individual. Indeed, one commentator has suggested that this conflict indicates what he regards as a fatal structural defect in the managed care industry. He writes:

> Physicians are sworn to their conscience—and their medical malpractice insurers—to do what is best for every individual patient; managed care operators are sworn to their shareholders to do what is cheapest for the entire population. People are not populations, at least not in the United States.[58]

It was quite clear in the discussion of the MCO that the payer was the true customer of the MCO. When we ask who is the true customer of the provider, the answer is not so clear. Certainly the MCO is the payer. But whether in our current situation the priorities of the payer have permeated the health care system is not clear. The providers themselves, both institutional and individual, vehemently maintain their commitment to the interests of the individual patient, not primarily to resource management.[59] And in national polls, even respondents who express distrust of the system often indicate their belief that their physician will provide for them the optimum treatment for their individual condition.[60] On the other hand, the effect of the variance control techniques and reimbursement mechanisms introduced by some MCOs are having an effect on practice patterns. Public physician resistance to MCO constraints on treatment options has certainly contributed to widespread uncertainty in the population at large. The very public debate on the potential consequences of reimbursement refusal of recommended treatments has begun to erode the public perception of the quality of care individuals can expect from their providers—even when the intention of the provider is to offer the patient the highest level of quality available.

In a policy study, "A Reality Check: The Public's Changing View of our Health Care System," the National Coalition on Health Care (NCHC)[61] states that a summary of 22 other national surveys taken between April 1996 and January 1998 reveals a clear pattern. Consumer concerns about health care are increasing and have grown from a narrow focus with individual elements of the health care system to broader, system-wide concerns. People are worried about: 1) their present and future ability to pay for health insurance and medical care, 2) the increasing difficulty of gaining access to necessary care when coverage is lacking or inadequate, and 3) the quality of medical care.

In the NCHC's 1997 Coalition Survey, thirteen statements dealt directly with perceptions of the quality of health care. The responses to many of these statements revealed very high levels of concern about health care quality. The vast majority of Americans agreed with the statement "there is something seriously wrong with our health care system." Eighty-seven percent agreed that "the quality of medical care for the average person needs to be improved," and only 15 percent had "complete confidence" in hospital care.[62]

Market model strategies of industrial productivity work very successfully in manufacturing because of the alignment of the means and the ends. The goal is customer satisfaction. By scrutinizing the processes by which the product is developed, the producer can constrain costs, and thus the price to the customer, while keeping the question of quality firmly in mind. The process is self-correcting, because the payer, as the consumer, is the arbiter of quality. A dissatisfied customer will not purchase the product.

The incentive structure that works so successfully in industry produces anomalies when it is applied to health care, because the payer is not the consumer. Patient preferences as to how to prioritize between cost and quality have

no structural role to play when the TQM model is applied to health care. The belief that quality can be improved by attention to processes of the delivery of care is widespread within health care and justified by reference to the success of CQI efforts in many other industries. But business mechanisms that control costs don't necessarily improve quality. Care providers, not cost administrators, are the best sources of quality control information and are most likely to be successful in implementing quality improvement processes.

JCAHO is urging provider organizations to introduce CQI methods, not for cost containment, but for improvement of quality of care. But paradoxically, introducing TQM mechanisms in the context of a split customer base, rather than preventing the erosion of quality, may hasten it, because of the way it emphasizes and responds to the priorities of the customer. Similarly, in its ratings of MCOs on the basis of reported consumer satisfaction, among other measures, the NCQA is trying to make it possible for employers and other payers to take quality as well as cost into consideration in purchasing decisions. The NCQA thus tacitly recognizes that it is the priorities of the true customer—the payer—that need to be influenced. Cost containment is a different value than quality. Since the relation of the MCOs to the patient is secondary to their obligation to their payers, and mediated by their arrangements with the actual providers of care, the criteria by which NCQA evaluates the quality of health care plans are less directly connected to the patients' criteria for quality, and likely will be effective only insofar as they begin to influence the purchasing decisions of the MCO's primary customer, the employer or government agency.

If the patient has vanished as a determinant of quality, the patient remains as the justification for the health care system and the designated recipient of its benefits. But the introduction of TQM for improving the quality of health care delivery has, for rational structural reasons, not succeeded in adequately integrating patient expectations into the changing system, despite the hopes and efforts of advocates of TQM across the health care system. The health care system needs to balance cost and quality. This need cannot be met by a division of labor where one component of the system, the MCO, is given the task of constraining costs, and different components, the providers, are made responsible for quality. The system as a whole cannot operate responsibly if the ethical obligations—to resource distribution on one side, and to patient interests on the other—drive its various stakeholder groups in opposing directions. Providers need to pay attention to the cost as well as the quality of the care they provide. MCOs must acknowledge quality as well as cost in arrangements with providers.

Like much in health care, determining what counts as high quality of care is complex. The methods for providing evidence of quality in care are crude and need improvement. Different components of our complex health care system have different perspectives on what the criteria for quality should be. But defining, developing, and implementing methods for improving quality are central concerns for the health care system. Quality improvement efforts can contribute to this effort, but only as quality, not cost containment, measures. TQM and CQI

are neither the panacea for health care that its advocates had hoped for, nor the failure its critics have pronounced it; but a work in progress confronting serious structural obstacles.

3. Ethics and the HCO

We have looked at major components of the health care delivery system: the payer, the MCO, the HCO, the individual provider, the enrollee, and the patient. Managed care organizations and providers share a common goal of high-quality care for a reasonable cost. As resource managers, MCOs apply cost-constraint mechanisms such as lowered reimbursements to providers to encourage careful scrutiny of outcomes and processes, giving them incentives in turn to become more efficient and effective in their operations. With the explicit goal of improving quality of care, and with the perspective of patient care kept firmly in mind, TQM techniques have been and continue to be of positive value to providers.

A survey of the literature on quality in health care reveals that the most successful and least problematic applications of CQI in health care originate on, and are applied to, the provider level.[63] Even in a period characterized by severe cost constrains and shrinking reimbursements, some hospitals and systems have been able to introduce techniques and technologies to reduce medical errors, improve post-discharge outcomes, or improve their operations. Efficiency improvements that do not interfere with quality of care can allow HCOs to survive imposed cost constraints and continue to provide good care. So individuals and organizations on the provider level are finding some CQI techniques to be helpful for reducing waste, over- and under-utilization and medical errors—but only if they prioritize quality, which providers consider their primary obligation. But quality considerations and cost considerations need not, and sometimes do not, march in tandem. Some care improvements, such as system-wide upgrades of medical information technologies to prevent prescription errors, may be initially expensive. It seems a fair assumption that good medicine is good business, so institutions committed to investing in quality of care may be justified in expecting eventual savings, but current emphasis on cost containment at any price sometimes makes this long-term view difficult to adopt.

The component of the system that is best suited to scrutinize and improve quality of care is the provider component: the HCOs and their associated health professionals who deal most proximately with the patients, the actual consumers of care, whose health outcomes and trust in the health care system are that system's ultimate justification and goal. Because of the persistent problem of the bifurcation of the customer throughout the health care system, any application of TQM principles runs the risk of bringing about undesired and unforeseen consequences in the cost/quality balance. *When you have a mechanism that can produce ethically and practically problematic outcomes, it must be applied within a structure that pays attention to the implications of those outcomes.*

A recent but important force for the improvement of the quality of clinical care is the health care organization ethics movement. Health care organization ethics is designed to improve the ethical climate of HCOs, and to strengthen their power to give voice to patient priorities within the health care system.[64]

A positive ethical climate has at least two important characteristics. First, it is an organizational culture where the mission and vision of the organization inform its expectations for professional and managerial performance and are implemented in the actual practices of the organization. Second, a positive ethical climate is one that embodies a set of values that reflect societal norms for what the organization should value, how they should prioritize their mission, vision and goals, and how the organization and the individuals associated with it should behave. Thus, health care organization ethics directs attention to the values and ideals associated with the social role of the health care organization, and works to bring its activities at all levels of function in line with its mission of excellent patient care. It is its role in aligning all institutional activities with its mission that suggests an organization ethics program can serve as an ethical constraining force. The organization can carefully consider the ethical implications of business decisions that may have an impact on quality of care, taking into consideration the patient's perspective on what counts as quality. Of course in some cases, for an HCO experiencing economic stress, cost considerations may have to take priority, but open discussions and attempts to minimize ethically uncertain impacts can go some way toward ameliorating problematic outcomes.

Health care organization ethics owes its inception to the JCAHO 1995 mandate that requires the HCO to conduct its business and patient care practices in an honest, decent and proper manner.[65] A broader more process-oriented definition of health care organization ethics has been advanced by the Virginia Bioethics Network: "Organization ethics consists of [a set of] processes to address ethical issues associated with the business, financial, and management areas of health care organizations, as well as with professional, educational, and contractual relationships affecting the operation of the HCO."[66] These processes include articulation, application, and evaluation of the organization's mission and values statements. Since organization ethics encompasses all aspects of the operation of the HCO, it includes the hospitals' relationships with other organizations in the health care system, including the MCO; and compunctions about conditions of MCO contractual relationships can be negotiated with those contracting payers.

There are different approaches to implementing an organization ethics mechanism or program. One possible approach may be through expanding the membership and responsibilities of existing institutional ethics committees. Some institutions have an ethics officer. Compliance or continual quality improvement programs for the medical staff may be the primary site for the development of such efforts. Each path to formulating and supporting an appropriate ethical climate will have its strengths and disadvantages. But whatever the path to formulating an organization ethics program, it must meet two conditions. The first

condition is the commitment of the HCO's leaders to develop a positive ethical climate. Any attempt to enhance the ethical climate of the HCO without this commitment is bound to fail. The second condition is that any plan to enhance the ethical climate should be consistent and global in nature. In other words, maintaining high ethical standards throughout the institution becomes the responsibility everyone in the organization—not just a selected few.

Attention to the ethical climate of a provider organization requires supporting the ethical perspectives of patient care ethics, business ethics, and professional ethics and acknowledging the contributions of each to the overall ethics program. Organization ethics must work to integrate these perspectives into a unified program that promotes and sustains a positive ethical climate within each particular HCO. If health care is to be perceived as more than a commodity to be bought and sold in the market, then the development of a positive ethical climate in the organization that directly delivers health care is vital. It is an important contribution to fulfilling patient expectations and counteracting some of the unintended effects of transferring an industrial model of quality improvement to the complex area of health care delivery.

The HCO is in the ideal position to implement programs to improve clinical care within the parameters of its social mandate. It interacts directly with patients in patient care activities (which the MCO does not). The HCO is a major supplier of goods and services to the MCO, thus, it may be in a position to refuse to enter into a contractual relationship that may potentially do disservice to those it purports to serve. The HCO interacts directly with individual providers of health care services, and can support their commitment to their common goals of patient care. Most importantly, the mission of the HCO is excellent patient care. An organization that supports a positive ethical atmosphere and that has excellent patient care as its primary mission will encourage appropriate personnel to find processes, policies, and mechanisms to give voice to the silenced patient.

4. Conclusion

Managed care is blamed for many of the problems of the current health care system—including some for which it is not responsible. If MCOs are accountable for only cost containment and not quality, then efficient cost containment mechanisms are appropriate business techniques. If the results are ethically and practically problematic, then the system as a whole must readjust, and accountability relationships among the various components need to be adjusted accordingly. The TQM movement in health care is an attempt to bring quality into greater prominence on the MCO level, but cost constraint is such a strong imperative in health care that the results, so far, are disappointing.

It is to be hoped that at the end of our current period of transition, all the components of the health care system—the payers, the individual and organizational providers, and the new MCOs that are increasingly in charge of managing the

administrative aspects of health care—will be united in their priorities and objectives, and will work together to enhance the health and well being of those needing care. We sometimes seem far from this imagined state, but there are approaches to ensuring that the voice of patients can be heard even within a tightly constructed industrial business model. One approach we have discussed, which we believe has some chance of success, is through the HCO adopting as its goal the development and support of an ethical climate that is appropriate to its mission of excellent patient care.

This approach depends on the willingness of the HCO and its leadership to refocus attention on its primary customer, the patient. This means that the HCO will have to move beyond mere compliance with existing laws and regulations and it may require the HCO to make some difficult choices. However, until the HCO is willing to endorse, support, and maintain an ethical climate that is focused on providing excellent patient care, the industrial management model will continue to dictate the delivery of care, and health care will look more and more like a commodity shaped by, and delivered within, traditional business strategies.

Notes

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[1] Kassirer, J. (November 19, 1998). "Doctor Discontent," *The New England Journal of Medicine* 339(21): 1543–5. Editorial. Available at http://www.nejm.org/content/1998/0339/0021/1543 asp.

[2] Clancy, C. (1995). "Managed Care: Jekyll or Hyde?" *Journal of American Medical Association*, 273(4): 338–9.

[3] Gray, B. (January/February 1997), "Trust and Trustworthy Care in the Managed Care Era," *Health Affairs*, 16(1): 34–9.

[4] The National Malcolm Baldridge Quality Award is an annual award given to U.S. companies to recognize these companies for their business excellence and quality achievement. Afraid that the work of Juran, Deming, and other quality leaders would be ignored by American business, Congress initiated the award as a way of making American business aware of the importance of quality and ensuring that American business understood the importance of concepts associated with TQM. That the techniques associated with TQM are effective is evident in the calculation made in 1998 by the Commerce Department's National Institute of Standards and Technology that states that a hypothetical stock index made up of publicly traded U.S. companies that have received the Malcolm Baldridge National Quality Award has outperformed the Standard & Poor's 500 by almost 3 to 1. For information on the award visit http://www.quality.nist.gov/ and see "Ten Years of Excellence for America" at http://www.nist.gov/public_affairs/baldrdist.pdf for the statistic mentioned above.

[5] Blendon, R et. al. (July/August, 1998), "Understanding the Managed Care Backlash," *Health Affairs*, 17(1): 80–93 See also Kuttner, R., note 33.

[6] Bodenheimer, T. and Sullivan, K. (April 2, 1998), "How Large Employers are Shaping the Healthcare Marketplace," *The New England Journal of Medicine*, 338(15): 1084–7, available at http://www.nejm org/content/1998/0338/0014/1003 asp.

[7] The National Committee for Quality Assurance (NCQA) is a private, not-for-profit organization dedicated to assessing and reporting on the quality of managed care plans. The NCQA's mission is to provide information that enables purchasers and consumers of managed health care to distinguish among plans based on quality, thereby allowing them to make more informed health care purchasing decisions. The NCQA's efforts are organized around two activities, accreditation and performance measurement, which are complementary strategies for producing information to guide choice. Although the MCO accreditation program is voluntary and rigorous, it has been well received by the managed care industry, and almost half the HMOs in the nation, covering three quarters of all HMO enrollees, are currently involved in the NCQA Accreditation process. Visit www ncqa.org for more information.

[8] See Iglehart, J K. (September 26, 1996), "The National Committee for Quality Assurance." *The New England Journal of Medicine*, 335(13): 995–9, available at http://www.nejm.org/content/1996/0335/0013/0995.asp, for a discussion of why HMOs endorsed "quality" as a goal to pursue.

[9] The American Association of Health Plans (AAHP) represents more than 1,000 HMOs, PPOs, UROs, and other network-based plans The AAHP has endorsed a "Philosophy of Care" as their statement of quality in the health care delivery system. Member organizations are required to subscribe to this statement. The last declaration in the "Philosophy of Care" is, "We believe that access to affordable, comprehensive care gives consumers the value they expect and contributes to the peace of mind that is essential to good health." See http://www.aahp org/prncpls.htm for the AAHP's entire philosophy of care.

[10] Deming, W. E. (Winter 1981–1982), "Improvement of Quality and Productivity Through Action by Management," *National Productivity Review*, 1(1): 12–22

[11] See a listing of those companies that have been awarded the Malcolm Baldridge Quality Award. Companies in each category we have listed have won the award. See http://www.quality.nist.gov/winners/winlist.htm.

[12] Garrison, R. and Noreen, E (1997), *Managerial Accounting*, 8th ed. (Boston, Mass., Irwin McGraw-Hill), 200–202.

[13] Blumenthal, D and Kilo, C. M. (1998), 'A Report Card on Continuous Quality Improvement," *Milbank Quarterly*, 76: 625–648. See also Shortell, S. M., Bennett, C L., and Byck, G. R., "Assessing the Impact of Continuous Quality Improvement on Clinical Practice: What It Will Take to Accelerate Progress," in the same issue, pp. 593–624

[14] Ibid., 631.

[15] Information on the Joint Commission is available at http://www.jcaho.org. In 1992, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) added "Continuous Quality Improvement" to its regulations for health care accreditation. See the JCAHO's 1992 *Comprehensive Manual for Hospitals*

[16] Michael Millenson, a long-time observer of the American Medical Association, writes that by 1986 the *Journal of the American Medical Association* (*JAMA*) had embraced quality measurement and management as a legitimate and important tool to improve outcomes in health care delivery. See Millenson, M (May/June 1997), "Miracle and Wonder The AMA Embraces Quality Measurement," *Health Affairs*, 16(3) 183–194.

[17] Westphal, J. D , Gulati, R . and Shortell, S M. (1997), "Customization or Conformity? An Institutional and Network Perspective on the Content and Consequences of TQM adoption," *Administrative Science Quarterly*, 42(2): 366–394

[18] Blumenthal, D. and Kilo, C. M : see note 13

[19] See the website for NCQA, http://www.ncqa.org/ See especially http://www.ncqa.org/Pages/communications/news/excellentrel2 htm for statistics on the number of Americans in plans accredited by NCQA

[20] Quality Management and Improvement is the first standards category of NCQA accreditation guidelines. See http.//www.ncqa.org/Pages/programs/accreditation/mco/Mean4.htm for a discussion on this category by the NCQA.

[21] Blumenthal, D and Kilo, C. M.; see note 13, p 634.

[22] Blumenthal, D. and Kilo, C. M. (see note 13, p 634) refer in their footnotes to Berwick and Nolan (1998), "Physician as Leaser in Improving Healthcare," *Annals of Internal Medicine,* 128: 289–92. Shortell et al.; see note 13.

[23] Blumenthal, D. and Kilo, C. M., see note 13, pp. 638–639.

[24] This anomaly of the health care system was noted in 1995 by E. Haavi Morreim who writes: "[I]n this sense the term purchaser is systematically ambiguous; we could be referring either to patients or to payers." See Morreim, E. H. (1995), *Balancing Act: The New Medical Ethics of Medicine's New Economics* (Washington D.C.. Georgetown Press). 22.

[25] Buchanan, A. (August 1998), "Managed Care: Rationing without Justice, but not Unjustly," *Journal of Health Politics, Policy and Law,* 23(4): 617–34; see p. 619.

[26] Chassin, M. R. and Galvin, R. W. (September 16, 1998), "The Urgent Need to Improve Health Care Quality," *Journal of the American Medical Association,* 280(11): 1000–5.

[27] Ibid.

[28] Enthoven. A. C. and Vorhaus, C B. (May/June 1997), "A Vision Of Quality In Health Care Delivery," *Health Affairs.* 16(3): 44–57.

[29] Laffel, G. and Blumenthal, D. (November 1989), "The Case for Using Industrial Quality Management Science in Health Care Organizations," *Journal of American Medical Association,* 262(20): 2869–2873.

[30] Greco, P. J. and Eisenberg, J M. (October 23, 1993), "Changing Physicians' Practices," *New England Journal of Medicine.* 329(17): 1271–4. Available at http://www.nejm.org/content/1993/0329/0017/1271.asp. Also note that in 1989 there were an estimated 700 sets of guidelines developed by thirty organizations Today, 75 national organizations have produced some 1,800 sets of guidelines. while individual hospitals, managed care organizations, private researchers, and pharmaceutical manufacturers have developed thousands of other guidelines. See Gabel, J. (May/June), "Ten Ways HMOs Have Changed During the 1990s," *Health Affairs,* 16(3): 134–145, especially p. 142. See also Morreim, E. H., "In such a mixed-up setting it is only natural that health plans are uncertain as to who they are accountable. And it is no mystery that, with the multiplicity of players and goals. the very idea of measuring QC is regarded with confusion and suspicion" (Summer 1999), "Assessing Quality of Care: New Twists from Managed Care," *Journal of Clinical Ethics.* 10(2): 88–99.

[31] Gazmararian, J. et. al. (May/June 1997), "Maternity Experiences in a Managed Care Organization," *Health Affairs,* 16(3): 198–208

[32] Morreim. E. H. (March 1998), "Revenue Streams and Clinical Discretion." *Journal of American Geriatrics Society,* 48(3): 331–337: see pp. 331–332

[33] Kuttner R. (January 21, 1999), "The American Healthcare System—Employer Sponsored Health Coverage," *New England Journal of Medicine.* 340(3): 248–52.

[34] Ibid.

[35] Isaacs, S. (Winter 1996), "Consumers Information Needs: Results of a National Survey," *Health Affairs.* 15(4): 31–41.

[36] Kuttner R.: see note 33.

[37] Gabel, J. et al. (May/June 1999), "Class and Benefits at the Workplace." *Health Affairs.* 18(3): 144–50.

[38] Kuttner R.; see note 33.

[39] Ullman, R., Hill, J. W, Scheye, E. C., and Spoeri, R. K (1997), "Satisfaction and Choice: A View from the Plans." *Health Affairs*, 16(3): 209–217.

[40] Collins, K. S. and Schoen, C. (August 1997). "Managed Care, Choice, and Patient Satisfaction," *The Commonwealth Fund* available at http://www.cmwf.org/publist/publist.asp?CategoryID=3.

[41] Kutter, R.; see note 33.

[42] Collins. K. S and Schoen. C.; see note 40

[43] Bailit, M. (November/December 1997). "Ominous Signs and Portents: A Purchaser's View of Health Care Market Trends." *Health Affairs*. 16(6): 85–8

[44] Ibid.; see note 39, p. 86.

[45] Bailit, M.; see note 43 See his note 4.

[46] Kleinke, J. D. (1998), *Bleeding Edge—The Business of Health Care in the New Century* (Gatthersburg, Md.: Aspen Publishers), 11. Also see a biography of J D. Kleinke who *Managed Care Magazine* calls one of the 10 most important men in the history of managed care. See http://www.hs-net.com/JDKleinke_Biography.htm.

[47] Levit, K et al. (January/February 2000). "Health Spending in 1998 Signals of Change," *Health Affairs*. 19(1): 124–132

[48] Bodenheimer, T. and Sullivan, K. (2 April 1998). "How Large Employers Are Shaping the Health Care Marketplace." *New England Journal of Medicine*, 338(14). 1003–1007

[49] Gold. M. R., Hurley. R., Lake, T., Ensor, T., and Berenson, R. (1995), "A National Survey of the Arrangements Managed-Care Plans Make With Physicians," *New England Journal of Medicine*. 25: 1678–1683.

[50] Enthoven, A. C. and Vorhaus. C B.; see note 28, pp. 50–51.

[51] Blumenthal, D. (1996), "Effects of Market Reforms on Doctors and their Patients." *Health Affairs* (Millwood), 15(2). 170–184.

[52] Starr, P. (1982). *The Social Transformation of American Medicine* (New York, N Y.: Basic Books Publishing).

[53] Goldman, A. (1980). *The Moral Foundations of Professional Ethics* (Totowa, N J.: Rowman and Littlefield).

[54] See the National Institute of Health's website for details on the requirements of Institutional Review Boards It can be found at http://www.nih.gov. Also see *The Belmont Report: Ethical Guidelines for the protection of Human Subjects* (Washington. D.C · DHEW Publication, 1978). (OS) pp. 78–0012.

[55] Fletcher, J . Lombardo. P A., Marshall. M. F , and Miller, F G (eds.) (1995). *Introduction to Clinical Ethics*, 2nd ed (Frederick Md University Publishing Group, Inc.).

[56] Kassirer, J. (July 6, 1995), "Managed Care and the Morality of the Marketplace." *New England Journal of Medicine*, 333(1)· available at http://www.nejm.org/content/1995/0333/0001/0050.asp

[57] Goldsmith, M. (1997), "'Doing What's Best for Patients'· A Sesquicentennial Rededication." *Journal of the American Medical Association*, 277(16) 1265–1268 See also Pellegrino. E. D. (1995). "Interests, Obligations. and Justice· Some Notes toward an Ethic of Managed Care." *Journal of Clinical Ethics*, 6 312–317. The editors of the *New England Journal of Medicine* and other physician commentators maintain the adequacy of the professional/individual model See Kassirer. J. P. (August 6, 1998). "Managing Care. Should We Adopt a New Ethic?" *New England Journal of Medicine*, 339(6) 397–8. Angel. M., Kassirer, J P. (1996). "Quality and the Medical Marketplace: Following Elephants," *New England Journal of Medicine*. 35(12): 883–5.

[58] Kleinke, J. D.; see note 48, p 13

[59] See note 57, especially Angel and Kassirer

[60] Kao. A. C. et al (October 13, 1998), "Patients' Trust in Their Physicians: Effects of Choice, Continuity, and Payment Method." *Journal of General Internal Medicine*, 10 681–686.

[61] The National Coalition on Health Care (NCHC) describes itself as "the nation's largest and most broadly representative alliance working to improve America's health care." The Coalition, which was founded in 1990 and is non-profit and rigorously non-partisan, is comprised of almost 100 groups, employing or representing approximately 100 million Americans.

[62] See http://www.nchc.org for more information and an executive summary of the report.

[63] Enthoven, A. C. and Singer, S. J. (July/August 1998), "The Managed Care Backlash and the Task Force in California," *Health Affairs*. 17(4): 95–110. See especially p. 105 and their note 35.

[64] Spencer, E., Mills. A., Rorty. M., and Werhane. P. (2000). *Organization Ethics in Healthcare* (New York, N.Y.: Oxford University Press).

[65] Joint Commission for Accreditation of Healthcare Organizations (1996), "Patient Rights and Organizational Ethics: Standards for Organizational Ethics," *Comprehensive Manual for Hospitals*; see especially pp. 95–97.

[66] Spencer E. (1997). "Recommendations for Guidelines on Procedures and Process to Address 'Organization Ethics' in Health Care Organizations (HCOs)," Virginia Healthcare Ethics Network, printed in *Organization Ethics in Healthcare*, Appendix 1. See Spencer, E., note 64.

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