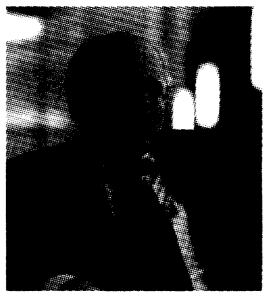

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OF DOCTORS AND HOSPITALS: SETTING THE ANALYTICAL FRAMEWORK FOR MANAGING AND REGULATING THE RELATIONSHIP*

James F. Blumstein**

TABLE OF CONTENTS

I. INTRODUCTION

The issues surrounding the movement toward integration of physician services and the institutional and economic interests of hospitals raise some of the most critical, delicate, and longstanding health policy and law issues confronting analysts and policymakers.

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* This Article is derived from the McDonald Merrill Ketcham Lecture, delivered in February 2007.

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1. How, and to what extent, should economic considerations factor into medical care decision making? That is, what is the proper relationship between technical medical/scientific factors and economic factors in the medical care decision making context? One traditional view – at one end of a continuum – suggests that the very introduction of economics into medical care decision making corrupts medical judgment and therefore should be avoided.[1] In that view, such conduct is sanctionable, even subject to punitive damages.[2] In some circles, this is still a prevalent point of view,[3] but some courts have recognized the inevitability of including economic factors in physician practice styles[4] while also recognizing that there are limits to the consideration of economics – a point beyond which the compromising of professional standards can fairly be labeled as the corruption of medical judgment.[5]

2. What is the appropriate role of physicians, as expert autonomous professionals, in medical care decision making, and, correlatively, what are the appropriate legal, institutional, and regulatory structures to shape that role?[6] Dealing with that set of questions quickly turns to a consideration of different ways of thinking about medical care – about different paradigms or models – and their assumptions and implications.[7] The hospital formatively was structured in reliance on and in response to one way of thinking about medical care – the professional-scientific paradigm. Over time, legal obligations and financial responsibilities have redefined and reshaped the hospital. Hospitals now typically have independent duties to patients[8] and responsibility for the quality

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[1] *See, e.g.*, Muse v. Charter Hosp. of Winston-Salem, Inc., 452 S.E.2d 589 (N.C. Ct. App. 1995), *aff'd per curiam*, 464 S.E.2d 44 (N.C. Sup. Ct. 1996).

[2] *Id.*

[3] For a general discussion of these issues, see James F. Blumstein, *Health Care Law and Policy: Whence and Whither?*, 14 HEALTH MATRIX 35 (2004).

[4] *See, e.g.*, Pegram v. Herdrich, 530 U.S. 211 (2000) (recognizing the need to consider cost-benefit trade-offs in the managed care context); Sarka v. Regents of Univ. of Cal., 52 Cal. Rptr. 3d 810 (Cal. Ct. App. 2006) (allowing the student health service to terminate employment of a staff physician for relying too heavily on testing and too little on less expensive clinical medical judgment).

[5] *See* Wickline v. State, 239 Cal. Rptr. 810, 820 (1986), *rev. dismissed*, 741 P.2d 613 (1987) (recognizing necessity for and validity of cost-containment programs, but noting that "it is essential that cost limitation programs not be permitted to corrupt medical judgment.").

[6] For an important discussion of this issue, see M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919 (2002). For a different perspective, see Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002).

[7] *See, e.g.*, James F. Blumstein, *Health Care Reform and Competing Visions of Medical Care: Antitrust and State Provider Cooperation Legislation*, 79 CORNELL L. REV. 1459, 1459, 1463-86 (1994) (examining "the competing visions of medical care represented by the professional and the market-based economic paradigm" and "consider[ing] the implications of those visions for the development of public policy.") [hereinafter Blumstein, *Competing Visions*]. For a skeptical view of the market-based alternative to the traditional professional/scientific model, see M. Gregg Bloche, *The Invention of Health Law*, 91 CAL. L. REV. 247 (2003).

[8] Sword v. NKC Hosps., Inc., 714 N.E.2d 142 (Ind. 1999) (adopting corporate negli-

of care that occurs within their walls. Hospitals also have a responsibility to manage within economic parameters and to take into consideration the hospital's institutional interest in quality assurance, marketing and patient flow, and cost containment.

These new environmental realities call into question the traditional "workshop" model,[9] in which the hospital serves a role somewhat analogous to that of eBay, as a forum or catalyst for the practice of medicine and for the diagnosis and treatment of patients, but with few or no independent institutional interests at stake. New realities also call into question the tight regulatory vision of the hospital, with a separate medical staff with its own bylaws and, in some jurisdictions, independent legal status.[10] This traditional hospital structure has turned out to be ill-suited for certain new roles being thrust on hospitals. Integrated Delivery Networks ("IDNs") (of which physician-hospital joint ventures are an example) have emerged over the past twenty years in part as a response to these new, largely economic, circumstances and in part as a result of the adaptivity constraints on hospitals that stem from a tight, one-size-fits-all regulatory structure that traditionally has defined the organization and governance of hospitals. Part of this Article will describe evidence of how these IDNs have emerged and how they have worked.

This Article will conclude that the regulatory flexibility that currently governs IDNs, as contrasted with hospitals, is desirable because it allows responsiveness to new circumstances in the marketplace, even though the evidence of IDN performance is not what some of its advocates might have hoped for to this point. Nevertheless, although overall regulatory rigidity towards IDNs is modest, IDNs still face regulatory landmines, such as the anti-kickback law,[11] which could adversely affect IDNs' ability to adapt and respond to changes in health care and the health care marketplace.[12]

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gence standard for hospital liability).

[9] For a discussion of different models of the role of the hospital, see James F. Blumstein & Frank A. Sloan, *Antitrust and Hospital Peer Review*, LAW & CONTEMP. PROBS., SPRING 1988, at 7, 18-24; Philip C. Kissam et al., *Antitrust and Hospital Privileges: Testing the Conventional Wisdom*, 70 CAL. L. REV. 595 (1982); Mark V. Pauly & Martin Redisch, *The Not-for-Profit Hospital as a Physicians' Cooperative*, 63 AM. ECON. REV. 87 (1973).

[10] *Compare* Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805 S.W.2d 756 (Tenn. 1991) (holding medical staff bylaws to be a source of enforceable contract rights) *with* Mason v. Cent. Suffolk Hosp., 819 N.E.2d 1029 (N.Y. 2004) (holding that medical staff bylaws cannot serve as the basis for damages litigation).

[11] For discussions of the landmines imposed on market-oriented approaches by the anti-kickback law, see James F. Blumstein, *The Fraud and Abuse Law in an Evolving Health Care Marketplace: Life in the Healthcare Speakeasy*, 22 AM. J. L. & MED. 205 (1996) [hereinafter Blumstein, *Speakeasy*]; James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, HEALTH AFF., Winter 1996, at 118.

[12] For a discussion of general legal problems associated with different IDN forms, see Carl H. Hitchner et al., *Integrated Delivery Systems: A Survey of Organizational Models*, 29 WAKE FOREST L. REV. 273 (1994); *see also* John D. Blum, *Beyond the Bylaws: Hospital-Physician Relationships, Economics, and Conflicting Agendas*, 53 BUFFALO L. REV. 459 (2005) (exploring physician-hospital relations in the current marketplace context).

A demonstration project to be initiated in 2007 and to run for several years is designed to determine the risks and benefits of gainsharing,[13] in which physicians and hospitals better align incentives to achieve quality assurance and cost containment objectives.[14] That demonstration should provide a vehicle for assessing, more broadly, the appropriate regulatory structure for IDNs and hospitals. The existing anti-kickback law may have ample flexibility through its safe harbor provisions and advisory opinion process to modify its unforeseen adverse impact on potentially constructive organizational restructuring in a changed, market-driven environment.

In general, this Article concludes that a regulatory regime should maintain flexibility and the ability to adapt to entrepreneurial opportunities. Regulatory strategy should reduce its emphasis (as in traditional hospital regulation) on micromanaging details of how organizations and institutions are structured. Greater emphasis should be placed on consequences to worry about, such as anti-competitive effects or poor-quality outcomes. The objective of regulatory policy should be to develop a regulatory regime that is neutral to organizational form and that allows institutions and physicians to cooperate or compete according to market conditions, provided that competitive conditions are maintained and quality outcomes are properly encouraged.

II. BACKGROUND AND OVERVIEW

(1)

Just over thirty years ago, Clark Havighurst and I made the case that economics had an important role to play in medical care decision making.[15] Trade-offs had to be made in the allocation of medical care resources, and institutional design was important in structuring decision making so that someone had an incentive to consider costs in resource allocation matters.[16]

The battle over the soul of PSROs – Professional Standards Review Organizations – was the context in which organized medicine attempted to tamp

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[13] For a discussion of gainsharing and physician financial incentives, see Richard S. Saver, *Squandering the Gain: Gainsharing and the Continuing Dilemma of Physician Financial Incentives*, 98 NW. U. L. REV. 145 (2003).

[14] *See* Ctrs. Medicare & Medicaid Servs., U.S. Dep't Health & Human Servs., Physician-Hospital Collaboration Demonstration, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PHCD_646_Solicitation.pdf (demonstration project description and request for proposal).

[15] Clark C. Havighurst & James F. Blumstein, *Coping with Quality/Cost Trade-offs in Medical Care: The Role of PSROs*, 70 NW. U. L. REV. 6 (1975).

[16] *Id.* For other discussions of the importance of institutional structure and design, see James F. Blumstein, *Constitutional Perspectives on Governmental Decisions Affecting Human Life and Health*, LAW & CONTEMP. PROBS., Autumn 1976, at 231; Clark C. Havighurst et al., *Strategies in Underwriting the Costs of Catastrophic Disease*, LAW & CONTEMP. PROBS., Autumn 1976, at 122.

down the emerging policy concerns associated with rapidly escalating costs on public budgets as a result of Medicare and Medicaid. PSROs were designed as professionally-controlled peer review organization networks to help reduce the rate of increase in Medicare and Medicaid costs. Organized medicine aggressively sought to redirect the focus of the program to promotion of health care quality, resisting the cost-containment mission of PSRO originators.[17] Thirty-five years later that battle continues to rage; PSROs still exist, but the name of the organizations has morphed to Peer Review Organizations ("PROs"),[18] and, most recently, Quality Improvement Organizations ("QIOs"),[19] demonstrating that the naming and renaming of these entities reflect the agendas being pursued.[20]

A critical component of the Havighurst and Blumstein analysis was to draw a distinction between waste control and cost control. Waste control is the zero-benefit circumstance, what has come to be called "flat of the curve" medical care. Eliminating zero-benefit diagnoses and treatments is uncontroversial, and politicians love the discourse, because it seems that policy makers can achieve something for nothing – lower cost at no reduction in quality through the realization of true economies (i.e., improved efficiency). Undoubtedly, as John Wennberg and colleagues have shown, the opportunity for achievement of true economies – elimination of truly wasteful care – is available and should be pursued.[21] But, from an economics perspective, a more ambitious agenda is to challenge an incentive structure that results in high-cost care with small but only marginal benefits. The problem of cost control (as distinct from waste control) is "marginally productive, not unproductive, care."[22] Care deemed "unnecessary" is "neither wholly useless nor affirmatively harmful" but "could be rendered effectively and appropriately in a shorter time, in a less sophisticated facility, or on an outpatient basis."[23] In sum, a regime of cost control

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[17] *See* Havighurst & Blumstein, *supra* note 15, at 42 n.123 (discussing organized medicine's efforts to reorient the PSRO program from cost containment to quality assurance).

[18] The PSRO program became the PRO program in 1982. Timothy Stoltzfus Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Control Peer Review Organization (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J. 1, 5 (1989).

[19] INST. OF MED., MEDICARE'S QUALITY IMPROVEMENT ORGANIZATION PROGRAM: MAXIMIZING POTENTIAL 19-32 (2006) (describing and providing an overview of QIO program).

[20] For a proposal to use QIOs' authority to confer medical malpractice immunity in certain circumstances, see James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" As a New Role for QIOs?*, 59 VAND. L. REV. 1017 (2006).

[21] *See, e.g.*, John E. Wennberg, *Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers: Is More Better?*, THE COMMONWEALTH FUND PUBLICATION NO. 874, Dec. 13, 2005, at 4 (noting "striking regional variations in the proportion of early stage breast cancer patients who undergo lumpectomy" and identifying "idiosyncratic practice style" as the "major source of such widely varying discretionary surgery rates.").

[22] Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 444 (1988) [hereinafter Hall, *Institutional Control of Physician Behavior*].

[23] Havighurst & Blumstein, *supra* note 15, at 32.

would result in some forgoing of marginally beneficial care as insufficiently justified based on an evaluation of costs and benefits. This idea later gained traction in managed care, although that movement was not forthright in adopting this analysis or explaining it to consumers.[24]

(2)

Nearly twenty years ago, Mark Hall, a leading health law and policy commentator, noted that "[c]ost containment pressures will not relent until physicians have undergone a revolutionary change in behavior."[25] Changes in the health care environment, mostly from then-recently adopted prospective payment by Medicare ("DRGs"), created cost-based pressures on hospitals to manage within specified financial parameters. [26] However, while financial incentives such as prospective payment for hospitals create incentives for fiscal restraint and oversight, such payment-oriented initiatives often overlook the institutional and regulatory setting in which the incentives must be implemented.

Thus, cost-containment efforts such as prospective payment approaches are premised on an assumption that, through management intervention of some type, expensive physician behavior will change substantially.[27] This is the typical assumption of economically-focused, incentives-based interventions – that when incentives change, behavior changes. But, this general assumption, while often correct, can lead to unforeseen or unwanted consequences. If incentives are structured inappropriately, competition can have perverse consequences.[28] Therefore, attentiveness to institutional structure and design is critical in determining whether the outcomes that result from changed incentives are constructive or counter-productive.

In the hospital context, Hall demonstrated that traditional professional authority was reinforced by a "strong legal infrastructure" that created headwinds for management implementation of or inducement of changed physician behav-

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[24] For a graphical depiction of the distinction between waste control and cost control, see *id.* at 17. In 2004, Tennessee adopted a statutory definition of medical necessity in its TennCare program (a Medicaid demonstration) that expressly includes economic factors in the determination of medical necessity and therefore in the scope of a beneficiary's entitlement to coverage. To qualify as medically necessary, a diagnosis or treatment (among other things) must be the "least costly alternative course of diagnosis or treatment that is adequate for the medical condition of the enrollee." TENN. CODE ANN. § 71-5-144(b)(3) (2004).

[25] Hall, *Institutional Control of Physician Behavior*, *supra* note 22.

[26] Under the Medicare prospective payment system for inpatient care, a hospital is paid a certain sum for a patient's hospital stay based on a diagnostic category – a diagnosis-related group ("DRG"). In general, hospitals are at risk financially if the expenses associated with a hospital stay exceed the sum set prospectively by Medicare for the DRG.

[27] Hall, *Institutional Control of Physician Behavior*, *supra* note 22, at 448.

[28] For a discussion of this issue, see Blumstein, *Competing Visions*, *supra* note 7, at 1494-95 & n.174.

ior. The legal infrastructure insulated physicians from traditional management command-and-control techniques; in place of such direct controls, hospital managers were typically left with coax-and-cajole strategies, which made it particularly difficult for managers to effectuate counter-cultural behavior change in a professional setting.[29]

In the hospital setting, the organizational structure of the hospital, particularly the separate medical staff, supports and insulates professional autonomy of physicians who practice at a hospital.[30] A hospital's structure makes the initiation by management of behavioral change strategies of the medical staff a challenge for management and difficult to implement in a direct, authoritative way. The indirect management techniques characteristic of management of professionals are best suited to behavioral change consistent with the cultural norms of a profession. In the hospital management context, that means that quality improvement strategies, which are consistent with physicians' cultural norms, are likely to meet less resistance than cost-containment strategies, which tend to cut across the physicians' cultural grain. The introduction of economic considerations (e.g., cost containment) might well require structural changes in the institutional organization or design of the hospital, or both, which would better align the financial interests of the hospital and its physician staff.

Because of the primacy of the hospital in the health care arena at the time, Hall contended that the rigid, one-size-fits-all structure of the hospital had to be addressed if cost-containment initiatives were to succeed. Hall observed a "critical need to integrate" the physician staff and hospital management "to bring physicians within the institution's economic framework."[31] Absent change, the prospective payment system potentially posed an "explosive" problem because physicians and hospitals faced "diametrically opposed incentives."[32] That is, physicians faced unconstrained fee-for-service incentives to

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[29] The cultures of physicians and hospital administrators often clash. *See* Donald E. L. Johnson, *Medical Group Cultures Pose Big Challenges*, HEALTH CARE STRATEGIC MGMT, Nov. 1997, at 2. Unlike managers, physicians tend to be narrowly focused on individual patients, view resources as unlimited (or should be), and have a highly developed professional identity. STEPHEN M. SHORTELL, EFFECTIVE HOSPITAL-PHYSICIAN RELATIONSHIPS 12 (1991). For a skeptical discussion of the effect of financial incentives in clinical decision-making, see David M. Frankford, *Managing Medical Clinicians' Work Through the Use of Financial Incentives*, 29 WAKE FOREST L. REV. 71, 79-83 (1994) (discussing the belief structure that underlies physicians' ways of thinking about medical care). Coax-and-cajole techniques are likely to be more effective in bringing about changes in behavior in the name of quality assurance because quality of care (unlike cost containment) is consistent with traditional physician cultural mores. *See* DONALD M. BERWICK ET AL., CURING HEALTH CARE 164 (1990) (suggesting the use of physician leadership, training, and education to bring about improved quality through coax-and-cajole not command-and-control techniques).

[30] Maintenance of professional autonomy is a critical traditional value for physicians. *See* STEPHEN M. SHORTELL ET AL., REMAKING HEALTH CARE IN AMERICA 105-09 (1996); Blumstein & Sloan, *supra* note 9, at 22-24.

[31] Hall, *Institutional Control of Physician Behavior*, *supra* note 22, at 505.

[32] *Id.* at 507.

use resources, while hospitals increasingly were "subject to fiscal restraint" through prospective payment, which placed hospitals at risk financially.[33] For Hall, through some form of integration of the physician staff and hospital management, the "profession's grip on the internal organization of hospitals must be broken in order for cost containment to succeed."[34]

IDNs and physician-hospital joint ventures must be seen in light of Hall's prediction. The struggle for primacy in these evolving organizations is a manifestation of the ongoing struggle for dominance in medical care decision making. An important issue is whether the organizational structure and control reflected in hospitals will be reproduced or varied in the evolving institutional and organizational environment in which the regulatory structure does not command a predetermined outcome of the struggle.

(3)

Ten years ago, economist Jamie Robinson noted that organizational form should be seen as the "outcome of a competitive process in which particular forms survive" where they best perform the functions that need to be performed.[35] Robinson viewed joint ventures between hospitals and physicians as having certain "advantages of coordination without the disadvantages of bureaucratization."[36] Stephen Shortell, a commentator on Robinson's Article, recognized the advantages of institutional flexibility associated with specific organizational forms, but cautioned against "either-or" thinking that would embed a new institutional rigidity by creating "boxes of 'ideal types.'"[37] Shortell recommended maintenance of institutional flexibility and pluralism in institutional design.

As it has turned out, Shortell had good foresight. The IDNs of today come in many sizes, shapes, and structures. A critical benefit, which facilitates this type of pluralism in organizational form and design, is the lack of rigidity of organizational structure of the type that is imposed on hospitals by an entrenched and somewhat inflexible regulatory regime.[38] After two decades of

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[33] *Id.*

[34] *Id.* This is the vision of the economist – use financial incentives to effect cultural change – but experts who study organizations and their structure tend to be pessimistic about the prospects for such substantial changes, especially among professionals such as physicians. HARRISON TRICE & JANICE M. BEYER, THE CULTURES OF WORK ORGANIZATIONS 187 (1993); John G. Day, *Managed Care and the Medical Profession: Old Issues and Old Tensions The Building Blocks of Tomorrow's Health Care Delivery and Financing System*, 3 CONN. INS. L.J. 1, 12 (1996); Frankford, *supra* note 29, at 80.

[35] James C. Robinson, *Physician – Hospital Integration and the Economic Theory of the Firm*, 54 MED. CARE RES. REV. 3, 12 (1997).

[36] *Id.* at 21.

[37] Stephen M. Shortell, Commentary, 54 MED. CARE RES. REV. 25, 30 (1997).

[38] The rigidity in hospital organization and structure stems from accreditation standards of The Joint Commission (formerly known as the Joint Commission on Accreditation of Health

integrated models of medical care, with physician-hospital joint ventures being significant examples,[39] experience suggests that the regulatory regime should, following the recommendation of Shortell, maintain institutional pluralism. No single model of organizational form or design should be locked in from a regulatory perspective, contrary to the approach that has been followed with respect to hospital structure and governance. The objective of regulatory policy in this field should be the promotion of regulatory flexibility and neutrality – a regulatory regime that focuses on results and outcomes, not on structure or governance.

The Gainsharing Demonstration, planned to commence in 2007,[40] should provide a vehicle for evaluating the benefits and identifying the risks of physician-hospital models of integration.[41] It also should suggest approaches for revising existing regulatory pitfalls that can confront physician-hospital relationships. The challenges raised by the federal anti-kickback law will likely be a central focus of the regulatory component of the demonstration. The extraordinary breadth of that statute, which prohibits the knowing and willful use of remuneration (conceived of broadly) to induce or solicit referrals, has placed limits on some potentially promising uses of gainsharing and can serve as a trip wire for institutional arrangements that constitute technical violations. However, the anti-kickback law itself contains two important self-corrective mechanisms that can allow regulatory accommodation without the need for legislative reform – regulatory safe harbors that can immunize constructive behavior that might otherwise run afoul of the broad proscriptions of the anti-kickback law, and advisory opinions, which are essentially case-specific safe harbors and which are legally binding in authorizing certain arrangements despite potential violations of the anti-kickback rules.[42]

III. WAYS OF THINKING ABOUT MEDICAL CARE: THE DIFFERENT MODELS

As already alluded to in the first two Parts of this Article, there are several different approaches to thinking about medical care and their implications for public policy analysis. Specifically, these approaches include the professional/scientific model and the market-oriented model. At the threshold, however, it is important to recognize that these models are not intended to be exclusive or preclusive categories. Rather, elements of both models must exist side-by-side in the health care arena. The critical question for public policy is

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Care Organizations), state licensure laws, and Medicare regulations. For a discussion of these regulatory rigidities, see Blum, *supra* note 12, at 461-64.

[39] For a typology of organizational forms, see Carl H. Hitchner et al., *supra* note 12.

[40] *See supra* note 14 and accompanying text.

[41] *See* Gail R. Wilensky et al., *Gain Sharing: A Good Concept Getting a Bad Name?*, 26 HEALTH AFF. 58 (2007); *see supra* notes 12-13 and accompanying text.

[42] *See* CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY 462-63 (2d ed. 1998); Blumstein, *Speakeasy*, *supra* note 11; James F. Blumstein, *What Precisely Is "Fraud" in the Health Care Industry?*, WALL ST. J., Dec. 8, 1997, at A25.

where to place the emphasis in any given set of circumstances – to determine where along a continuum public policy should be directed.

A. The Professional/Scientific Model: Its Assumptions and Implications

The professional/scientific model reflects a response to perceived market failure.[43] It assumes a lack of knowledge on the part of patient-consumers and the scientific expertise of physicians – an asymmetry of information.[44] Patients are not knowledgeable and presumably incapable of becoming sufficiently informed so as to function as knowledgeable consumers in the medical care marketplace. In the face of consumer ignorance, the market cannot function well in the medical care arena.

The implication of this perception of market failure is that decision makers other than patients must be relied on. That is, professional providers, such as physicians, serve as substitute decision makers, displacing consumers. This vests tremendous authority in professionals, based on their scientific expertise, to make decisions that have not only scientific but also economic consequences. As substitute decision makers applying professionally-developed norms and practice standards, physicians under the professional/scientific model ultimately determine individual levels of quality and the volume of services for individuals (and ultimately aggregate levels of utilization and costs).

The professional/scientific model further assumes that diagnosis and treatment decisions are not influenced by financial incentives. Instead, such decisions are scientifically determined and are unrelated (or only marginally related) to financial incentives, as one would expect to be the case in a market-driven scenario. At one time, the claim that financial incentives do not matter was an empirical one. In the last thirty years, however, analysts now realize that economic incentives shape individual and patient decision making and influence the levels of utilization as well as the location in which care is provided (e.g., inpatient vs. outpatient). The claim that financial incentives do not matter now rings more of a normative than an empirical bell; that is, consideration of economics is, or runs the risk of being, corrosive to medical practice and therefore is inappropriate.

B. The Market-Oriented Model: Its Assumptions and Implications

The market-oriented response to market failure that stems from lack of

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[43] *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 226-27 (1982) (arguing that the professional/scientific model was not solely a response to market failure but a contributor to market failure in the service of professional dominance).

[44] *See* Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963), *reprinted in* 26 J. HEALTH POL. POL'Y & L. 851, 871-72 (2001) (identifying market failure in medical care and attributing it, in part, to an asymmetry of information between patients and physicians).

consumer knowledge is to provide information and education. The objective of public policy under this view is to improve the flow of comprehensible information to consumers so that they can function better as consumers. One way to achieve this goal would be through the use of information intermediaries to help consumers understand and process unfamiliar information.

The market-oriented approach normatively relies on the importance of patient autonomy – the traditional authority of patients to understand the issues surrounding and to give consent to medical interventions.[45] The impetus for more involvement of patients in their own care responds, at least in part, to a bottom-up concern with patient empowerment.[46] The market-oriented approach also has gained momentum from patients who have shown a remarkable ability to learn about their own (often life-threatening) illnesses and, newly knowledgeable, are eager to participate with their physicians in decision making about their medical situations.

Expanded information flow to patients has been stimulated by the emergence of patient-centered rules of disclosure under the doctrine of informed consent.[47] The Internet and other technological advancements have led to the burgeoning of accessible, comprehensible information, which has resulted in the emergence of a more knowledgeable (and, therefore, empowered) patient. Such patient empowerment is manifested in the shared decision making movement, which is characterized by physicians and patients sharing more even-handedly in a patient's medical diagnosis and treatment. These conversations between physicians and patients include medical and other (e.g., lifestyle and economic) factors that often inhere in a course of diagnosis and/or treatment.[48] Furthermore, evidence suggests that patients who participate in their own medical care decision making are more likely to adhere to appropriate courses of treatment.[49]

An important goal for advocates of a more market-oriented approach in health care is to develop an industry structured so that incentives are proper and private decision makers make both self-interested and socially appropriate decisions.

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[45] "Common law principles recognize personal autonomy by requiring consent before a physician is authorized to touch a patient. . . . To be effective, consent must be 'informed'." Blumstein, *Competing Visions*, *supra* note 7, at 1474. For a discussion of the informed consent doctrine, see Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L. J. 899 (1994).

[46] *See* Blumstein, *Competing Visions*, *supra* note 7, at 1475 & n.66.

[47] *See id.* at 1474-75 (discussing the doctrine of informed consent as an inroad on the traditional professional/scientific paradigm).

[48] *See, e.g.*, Joseph F. Kasper et al., *Developing Shared Decision-Making Programs to Improve the Quality of Health Care*, 18 QUALITY REV. BULL. 183 (June 1992) (discussing risks of prostate surgery and choices of men about surgical and non-surgical treatment alternatives).

[49] Blumstein, *Competing Visions*, *supra* note 7, at 1475.

IV. THE HOSPITAL AS THE EMBODIMENT OF THE PROFESSIONAL/SCIENTIFIC MODEL

The organization and structure of the modern American hospital are driven by a regulatory regime that requires the existence of a separate medical staff within the hospital.[50] The separation between general administrative governance and medical staff governance within the hospital is a tool to ensure that professional autonomy in medical decision making will be free from lay influence or control[51] and has a rationale akin to that of the traditional doctrine that banned or restricted the corporate practice of medicine.[52] That is, physicians must be solely responsible for making scientifically-determined medical judgments without interference with those decisions by hospital administrative officials.[53] In some jurisdictions, the medical staff bylaws constitute binding and enforceable contractual obligations, which limit the authority of the hospital to make decisions about appointing or retaining its medical staff.[54]

The assumption underlying the regulatory-imposed hospital structure is well illustrated by *Muse v. Charter Hospital of Winston-Salem, Inc.*[55] *Muse*

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[50] *See* Blum, *supra* note 12, at 461-64; Hall, *Institutional Control of Physician Behavior*, *supra* note 22, at 528-32 (providing a good background on the topic). The hospital structure has been referred to as "tripartite" because it contemplates a "board, medical staff, and administration." Blum, *supra* note 12, at 460. This structure is not happenstance but instead imposed by a universal regulatory regime that includes state licensure law, Medicare, and accreditation standards adopted and implemented by The Joint Commission. *Id.* at 461-63.

[51] *See* Blumstein & Sloan, *supra* note 9, at 10-12 (discussing the historical evolution of the separate medical staff in the hospital setting).

[52] *See* Arnold Rosoff, *The Business of Medicine: Problems with the Corporate Practice Doctrine*, 17 CUMB. L. REV. 485 (1987); Jeffrey F. Chase-Lubitz, Note, *The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry*, 40 VAND. L. REV. 445 (1987) (discussing the corporate practice of medicine doctrine). The corporate practice doctrine "prohibits corporations from providing professional medical services" and "is primarily inferred from state medical licensure acts, which regulate the profession of medicine and forbid its practice by unlicensed individuals." Berlin v. Sarah Bush Lincoln Health Ctr., 688 N.E.2d 106, 110 (Ill. 1997). One important underlying public policy concern is the "danger[] of lay control over professional judgment." *Id.*

[53] *See* Beverly Cohen, *An Examination of the Right of Hospitals to Engage in Economic Credentialing*, 77 TEMP. L. REV. 705 (2004) (discussing the question of whether hospitals can make credentialing decisions on a basis other than professional competence). The Joint Commission Accreditation Manual describes credentialing as follows: "Credentialing involves the collection, verification, and assessment of information regarding three critical parameters: current licensure; education and relevant training; and experience, ability, and current competence to perform the requested privilege(s)." THE JOINT COMMISSION, 2007 COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK MS-15 (2007). Although these terms do not necessarily preclude the use of economic factors, they also do not explicitly include them. *Id.*

[54] Lewisburg Cmty. Hosp., Inc. v. Alfredson, 805 S.W.2d 756, 759 (Tenn. 1991); *but see* Mason v. Cent. Suffolk Hosp., 819 N.E.2d 1029, 1030 (N.Y. 2004).

[55] Muse v. Charter Hosp. of Winston-Salem, Inc., 452 S.E.2d 589 (N.C. Ct. App. 1995),

involved a mental health patient with thirty days of inpatient insurance coverage.[56] As the thirty days wound down, the hospital engaged in a process of discharge planning, leading to the patient's discharge to a public mental health authority for outpatient treatment.[57]

Under conventional doctrine, hospitals are not permitted to abandon patients, but they may transfer patients to other suitable facilities. The question is whether the alternative facility is suitable to the needs of the patient.[58] Under the conventional doctrine, the abandonment inquiry in *Muse* would have focused on the suitability of the public mental health outpatient service to which the patient had been discharged. Instead, the court used a different analysis and held that a "hospital has the duty not to institute policies or practices which interfere with the doctor's medical judgment."[59] Although the doctor signed the patient's discharge papers, the hospital was found liable for wanton and willful conduct since it adopted a policy of discharge planning that seemed to the court to require patient discharge upon the expiration of the patient's insurance coverage.[60] Since the physician actually discharged the patient, the hospital was liable because it adopted a policy or practice that "interfered with the medical judgment" of the patient's attending physician.[61] One interpretation of what it meant for the hospital to "interfere" with the physician's medical judgment was that the hospital expected the physician to include in his decision making the consideration of the economic reality that the patient's insurance coverage was about to (and did) expire.

The organization and structure of the hospital, therefore, seem to reflect an assumed need to insulate the members of the physician staff from the consideration of cost and other non-medical factors in their decision making. *Muse* shows a very low threshold for concluding that professional medical judgment is corrupted – encompassing, in the *Muse* case at least, the possibility that any consideration of economic factors in a physician's decision making process is an impermissible corruption of professional medical judgment.

The organization and structure of the hospital bear a certain resemblance to the structure of a university in which members of the faculty are autonomous on matters of educational decision making and protected under the norm of academic freedom from inappropriate administrative oversight. The separate medical staff contemplates a model of governance in which physicians enjoy medical governance prerogatives akin to the academic freedom of university faculty. This structure suggests very limited control by hospital administration and is consistent with viewing hospitals as a physicians' workshop. This traditional "workshop" vision of the hospital can be referred to as an eBay model of

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aff'd per curiam, 464 S.E.2d 44 (N.C. Sup. Ct. 1996).

[56] *Id.*, 452 S.E.2d at 593.

[57] *Id.*

[58] *See* Payton v. Weaver, 182 Cal. Rptr. 225 (1982).

[59] *Muse*, 452 S.E.2d at 594.

[60] *Id.*

[61] *Id.*

hospital governance and function.

In this vision, hospitals are not seen as having independent institutional interests; they are locations or forums in which patients receive care and physicians practice their profession. This structure, however, raises questions about routine management decisions that can affect the institutional interest of a hospital. For example, hospitals may seek to contract selectively or exclusively with certain physicians or physician groups for a variety of institutional reasons related to cost and/or quality issues. This raises the issue of economic credentialing – can hospitals base staff decisions on criteria other than physician competence?[62]

The question of economic credentialing demonstrates the tension between the traditional "workshop" or eBay vision of the hospital and the emerging reality that hospitals have their own institutional interests that need to be addressed and accommodated. Once it is recognized and acknowledged that hospitals have their own institutional interests, it becomes axiomatic that they will need to develop mechanisms by which they can attend to those interests.[63] Physicians practicing within a hospital have a strong influence on the hospital's institutional interests related to such issues as medical errors, overall quality of care (and attendant concerns about reputation and liability), and cost of care (with hospitals often financially at risk for consistently above-average costs of services). Under such circumstances, it is important that medical practice in hospitals be brought in from the economic cold. Since hospitals have their own institutional interests, it is no longer desirable or probably even viable for medical practice within a hospital to remain outside the economics of the hospital or outside the authority structure of the management of the hospital.[64]

In a world where organizational form is the "outcome of a competitive process in which particular forms survive" because they best perform the functions that need to be performed,[65] it is not surprising that hospitals would seek to develop and embrace organizational forms and structures that better accommodate their own institutional interests and objectives. The built-in rigidity of

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[62] See Cohen, *supra* note 53, for a discussion of economic credentialing.

[63] See Blumstein & Sloan, *supra* note 9, at 91, for an interesting discussion of how antitrust law can help to encourage hospital decision making more nearly to reflect the "mode of decisionmaking of more traditional economic entities such as firms." Blumstein and Sloan argue that "historically entrenched attitudes, professional prerogatives, economic dependence, institutional structural rigidities, and legal doctrines have created headwinds against the kind of hospital role" in which hospitals "will generally act in accordance with consumer interests to the extent that the external environment permits." *Id.* They advocate use of antitrust doctrine more aggressively "in compelling hospitals to act more like competitive economic entities." *Id.* Concentrating on "the most risky areas – physician cartel behavior," they recommend that "hospitals shoulder the burden of demonstrating the procompetitive character of decisions that, based on history and the insights of social science research, one can reasonably label prima facie anticompetitive." *Id.*

[64] *See* Hall, *Institutional Control of Physician Behavior*, *supra* note 22, at 507.

[65] Robinson, *supra* note 35, at 21.

the regulatory regime governing hospitals predictably led to the pursuit of other mechanisms that better perform certain functions that need to be performed. This might include bringing economic and other non-medical factors into the decision making process and seeking greater hospital authority to assert quality-enhancement and cost-containment objectives.

V. THE EVOLVING EXTERNAL ENVIRONMENT AND ITS IMPACT

A conclusion in Part IV was that the traditional "workshop" or eBay model of the hospital is no longer appropriate because hospitals increasingly have independent institutional interests that need to be addressed and accommodated. This Part will identify and explain two of the most significant external factors that have led to the evolution of these independent institutional interests of hospitals.

A. Quality of Care

The first factor is a hospital's interest in promoting and managing the quality of care, including medical errors, that is provided in the hospital. This interest has both a positive and a negative component.

The positive component concerns a hospital's desire to promote its own reputation for quality and for managing effectively to assure quality[66] in a market-driven, competitive environment.[67] To achieve this objective, hospitals have an incentive to seek out organizational structures that allow hospital management more directly to design and implement quality-enhancement strategies that are consistent with the hospital's interest in promoting its reputation for quality. Pursuit of this institutional objective is particularly appropriate in light of the revelation by the Institute of Medicine of the degree to which medical errors occur in hospitals and of the systemic nature of those errors,[68] which not only lend themselves to an institutionally-oriented response but require it.[69]

The negative component of a hospital's interest in quality of care is that hospitals are increasingly responsible from a liability perspective for medical

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[66] See William M. Sage & Peter J. Hammer, *A Copernican View of Health Care Antitrust*, LAW & CONTEMP. PROBS., Autumn 2002, at 241, 252-53, for a discussion of the hospital's interest in promoting quality for its own institutional, competitive reasons in a managed care setting.

[67] See Thomas E. Kauper, *The Role of Quality of Health Care Considerations in Antitrust Analysis*, LAW & CONTEMP. PROBS., SPRING 1988, at 273, for a discussion of the procompetitive aspects of promoting health care quality in a competitive, market-based environment.

[68] *See* INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (1999).

[69] See James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace?*, 11 ANNALS HEALTH L. 125 (2002), for a discussion of the liability implications of the IOM findings.

mal-occurrences that transpire within their four walls. The hospital's liability risk has grown along two related but distinct pathways – direct and vicarious liability.

Increasingly, there is a recognition that hospitals have a direct duty to their patients in the following four areas: (i) to maintain safe and adequate facilities and equipment; (ii) "to select and retain only competent physicians;" (iii) to oversee all persons who practice medicine and provide patient care within their walls; and (iv) to formulate, adopt, and enforce rules and policies to ensure quality of care for patients.[70] The breach of a direct duty to a patient can result in liability. Clearly, the hospital's direct duty to assure the provision of quality care to patients being treated within its walls places a managerial responsibility on the hospital as an institution. In turn, such responsibility leads hospital administrators to be concerned about how to implement that responsibility and to ensure compliance given the governance structure of hospitals. For example, the separate medical staff structure provides hospital managers with limited direct authority with respect to the selection or retention of physicians, even though the hospital incurs liability for a failure to select and retain only competent physicians.[71] In sum, even though hospitals are typically left to manage by coax-and-cajole, not command-and-control, they are responsible, nevertheless, for assuring the non-negligent provision of quality care for patients.

Hospitals also have faced vicarious liability for negligence in patient care. For employees (e.g., physicians and nurses), the traditional doctrine of respondeat superior has been applied to hospitals.[72] In the hospital setting, even though most physicians with practice privileges are not hospital employees, courts increasingly have imposed vicarious liability on hospitals under principles of ostensible agency.[73] Under ostensible agency doctrine, a principal should be held liable for the negligent conduct of its agent if the person dealing with the agent had a reasonable belief (for which the principal can be held accountable) that the agent was authorized to act for its principal.[74]

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[70] *See, e.g.*, Thompson v. Nason Hosp., 591 A.2d 703, 707 (Pa. 1991) (describing the hospital's duties). *See generally* Sword v. NKC Hosp., Inc., 714 N.E.2d 142 (Ind. 1999) (adopting corporate negligence standard for hospital liability).

[71] *See* Elam v. College Park Hosp., 183 Cal. Rptr. 156, 162-64 (Ct. App. 1982) (recognizing that although peer reviews for quality purposes are conducted by the independent medical staff, the hospital itself is ultimately responsible for assuring quality and failure in that process leads to liability under the doctrine of corporate negligence).

[72] *See, e.g.*, McDonald v. Hampton Training Sch. for Nurses, 486 S.E.2d 299 (Va. 1997) (finding hospital liable for negligence of physician when physician is an employee of the hospital); Bernardi v. Cmty. Hosp. Ass'n, 443 P.2d 708, 713 (Colo. 1968) (applying respondeat superior principles to hospital liability for negligence of nurse employee).

[73] *See, e.g.*, Grewe v. Mount Clemens Gen. Hosp., 273 N.W.2d 429, 434-35 (Mich. 1978).

[74] *See, e.g., id.* at 434. Under *Grewe*, a plaintiff is obligated to establish (1) the patient had a reasonable belief in the agent's authority; (2) the patient's belief was generated by an act or the neglect of the hospital; and (3) the patient is not negligent – that is, the patient reasonably

One troubling concern with imputation of liability under ostensible agency is that the doctrine focuses analytically (in substantial part) (a) on the reasonableness of the patient's belief that the physician was the agent of the hospital and (b) on the conduct of the hospital in creating, reinforcing, or disabusing patients of that perception. The questions of patient perception and the reasonableness of the hospital's conduct in either reinforcing or offsetting that perception may not address the real underlying concern – finding a satisfying doctrinal substitute for respondeat superior in the absence of an employer-employee relationship. There is a considerable question as to whether the application of the ostensible agency doctrine in the hospital context has intellectual integrity or whether it is an intellectual halfway house.

To have doctrinal integrity, the ostensible agency doctrine must allow a hospital to defend against liability by successfully challenging the reasonableness of a patient's belief that a physician is an agent of the hospital. Yet in *Grewe*, an ostensible agency case, the Michigan Supreme Court left open the question of what the result would be "if plaintiff knew or should have known" that the relationship of the physician and the hospital was not that of agent and principal.[75] Given the nature of the doctrine and the elements of the doctrine, it is startling to have the *Grewe* court leave that issue open. Other courts applying ostensible agency or a variant (agency by estoppel)[76], however, have declined to give effect to obvious notices placed in an emergency room for the purpose of notifying the patient that the physicians practicing in the emergency room were independent contractors and not employees of the hospital.[77] This type of holding, which seems to challenge the doctrinal core of ostensible agency,[78] calls into question the integrity and viability of the doctrine in the hospital setting.

The doctrinal inadequacies of ostensible agency have led some courts to look for a more satisfying doctrine – one imposing on hospitals a non-delegable duty to assure non-negligent patient care within the hospital. Some courts have been reluctant to embrace the concept,[79] and even when embracing the concept in the context of an emergency room, courts accepting the doctrine have modified it. For example, in *Simmons v. Tuomey Regional Medical Center*, South Carolina purported to accept the non-delegation principle, imposing a non-delegable duty on hospitals to ensure the rendering of competent service to patients in the emergency room setting.[80] The *Simmons* court was critical of os-

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relied on his or her perception of the physician as the agent of the hospital. *Id.*

[75] *Id.* at 435.

[76] *See* Baptist Mem'l Hosp. Sys. v. Sampson, 969 S.W.2d 945, 947 n.2 (Tx. 1998) (noting that "[m]any courts use the terms ostensible agency, apparent agency, apparent authority, and agency by estoppel interchangeably" and that, "[a]s a practical matter, there is no distinction among them.").

[77] Clark v. Southview Hosp. & Family Health Ctr., 628 N.E.2d 47, 54 (Ohio 1994).

[78] See *Baptist Mem'l Hosp. Sys.*, 969 S.W.2d at 950, for an example of a court giving effect under ostensible agency to hospital signage that informed emergency room patients of the physician-hospital relationship.

[79] *See, e.g., id.* at 948-49.

[80] Simmons v. Tuomey Reg'l Med. Ctr., 533 S.E.2d 312, 322 (S.C. 2000).

tensible agency as a rationale for hospital liability because (i) it believed that requiring a finding that the hospital acted culpably in representing that it was the principal and the physicians were its agents was inappropriate and unnecessary and (ii) it believed that proof of the patient's reliance on the hospital's representation was also inappropriate and unnecessary.[81] Accordingly, the court imposed, as a matter of policy, a non-delegable duty on hospitals to render competent care to patients in its emergency room.[82] In describing the nature of the non-delegable duty, however, the *Simmons* court reintroduced many of the elements of ostensible agency such as the reasonableness of the patient's belief that the physician was a hospital employee.[83]

While the courts still struggle with the appropriate doctrinal formula for vicarious liability, the fact remains that courts have expanded hospitals' liability for the medical maloccurrences of their physicians and other medical care providers. Hospitals, regardless of whether they are positively seeking to advance quality as a reputation-based marketing plus or negatively concerned about the liability risks of poor quality and high error rates, are confronted with a situation in which hospital management needs to address and accommodate rationally the hospitals' own institutional interests. To the extent that the existing hospital organization and governance structure is not conducive to the pursuit of hospitals' own institutional interests regarding quality assurance, they are predictably going to seek out alternative arrangements and institutional structures that allow more direct hands-on management of the hospital for the achievement of quality of care objectives.

B. Cost Containment

The hospital's structure makes the introduction of economic considerations difficult. As noted previously, the hospital's structure is reflective of the professional/scientific model in which economic considerations are marginalized.[84] The structure of the hospital assumes that medical decision making is largely technical, exclusively a matter of scientific expertise, and entirely within the sphere of autonomous physician control. This rigid one-size-fits-all structure is an impediment to effective cost-containment initiatives implemented by hospitals. Because cost containment is counter-cultural for physicians, and because the hospital governance structure compels reliance on coax-and-cajole techniques rather than command-and-control techniques of management, achieving hospitals' institutional cost containment objectives is even more of a challenge than achieving a hospital's quality of care objectives.[85]

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[81] *See id.* at 320-21.

[82] *Id.* at 322.

[83] *Id.* at 323.

[84] *See supra* Parts III.A, IV.

[85] *See* Frankford, *supra* note 29; Jonathan J. Frankel, Note, *Medical Malpractice Law and Health Care Cost Containment: Lessons for Reformers from the Clash of Cultures*, 103

Yet, for hospitals, addressing and coping with cost containment pressures have become more acute concerns. In his work on hospitals and cost containment, Mark Hall noted a "critical need to integrate" the physician staff and hospital management "to bring physicians within the institution's economic framework."[86] He also noted, however, the institutional constraints that impeded that development.[87]

The shift in the way hospitals are paid – by Medicare and some private insurance carriers – has resulted in hospitals being expected to assume financial risk that they had not previously been expected to absorb. Previously, hospitals had been paid on a retrospective reimbursement basis, premised on cost reimbursement. If patients have insurance in such an environment, hospital finance is relatively straightforward. Hospitals spend money on patient care, and insurance carriers reimburse those expenditures. In such circumstances, hospitals have no substantial independent financial interests; they are not at risk financially.

When Medicare adopted a prospective payment system for inpatient hospital services in the 1980s, however, hospitals were expected to operate within preset fiscal parameters. If they did not manage their costs, they could no longer seek after-the-fact reimbursement for excess costs as they had done in the past. Instead, hospitals' revenues were limited to the amount of the prospective payment set by Medicare. A similar dynamic resulted from private insurers and health plans, which placed financial limits on hospitals through discounted pricing or capitation payment approaches. These tighter fiscal constraints imposed independent financial interests on hospitals, but the traditional hospital organizational and governance structure was premised on a model that assumed away the significance and even the legitimacy of cost considerations in medical care decision making.

The evolution of the health care marketplace allowed hospitals to pursue different roles, providing an opportunity for hospitals to reverse, to some extent, the power relationships with doctors – for example, by bidding for managed care contracts with health plans, thereby securing control of patient flow and channeling patients to physicians. The market and the confining structure of the hospital provided an incentive and an opportunity for hospitals to break out of the traditional "workshop" type of physician-hospital relationship. Sometimes, hospitals have incentives to cooperate with physicians, and sometimes they prefer strategically to compete with physicians. These new relationships, however, are occurring outside the traditional hospital-physician relationship structure.

The various models of physician-hospital relationships emerged in response to the reality that medical care is functioning in a market-based envi-

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YALE L.J. 1297 (1994), for a discussion of the problem of cost containment from the perspective of a hostile physician culture.

[86] Hall, *Institutional Control of Physician Behavior*, *supra* note 22, at 505.

[87] *Id.* at 505-07.

ronment. They reflect a shift towards greater recognition and acceptance of market-based assumptions and realities. The traditional confining hospital structure was crafted under the controlling assumptions of the professional/scientific paradigm. The newer and still-emerging physician-hospital relationships that are developing outside the traditional hospital structure are entities and relationships that are premised on market-oriented principles and adaptive to the emergence of and legitimation of the market-oriented paradigm. IDNs, therefore, cannot be understood outside the need for physicians and hospitals to develop new structures to manage costs and promote quality (as good business practices).

VI. THE EVOLUTION OF INTEGRATED DELIVERY NETWORKS

As the above theoretical discussion suggests, there appears to be a consensus among empirical scholars who have studied the matter that physician-hospital integration "reflects providers' organizational responses to competitive pressures from rapidly expanding managed care health insurance."[88] That is, IDNs reflect the influence of and are a response to the emergence of the market model. They reflect no single prototype and can be led by hospitals or by physician groups.[89]

A. Competing Hypotheses and Rationales

The question has arisen as to the likely consequences of hospital-physician integration. Is such integration likely to result in efficiency gains? That is, do the more efficient integrated organizations offer *lower* prices to managed care plans through lower levels of utilization or other efficiencies in the production of medical care services? Or, alternatively, is integration really an attempt by providers to improve bargaining power (through enhanced market power) with managed care plans? Such a story would suggest *increased* prices instead of lower prices[90] and would also suggest that the IDNs were not designed or used for a fundamental restructuring of the physician dominance that characterized the traditional hospital structure and that had stemmed from a non-market-based premise.

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[88] Allison Evans Cuellar & Paul J. Gertler, *Strategic Integration of Hospitals and Physicians*, 25 J. HEALTH ECON. 1, 1 (2006).

[89] For typologies of various forms of IDNs, see *id.* at 8-11; Hitchner et al., *supra* note 12.

[90] This market-power scenario was a concern expressed by the recent report of the U.S. Department of Justice and the Federal Trade Commission. FED. TRADE COMM'N & DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION 13 (2004) (Executive Summary).

B. The Evidence

Although the evidence is not uniform on the issues,[91] there is considerable evidence that hospitals with an integrated organizational structure do not have lower costs than unintegrated hospitals.[92] Hospital-physician integration seems to be a "strategic response to counter the rising monopsony power of managed care and is one of the sources of the recent increase in health care costs."[93]

That is, much evidence seems to support the market-power explanation of IDNs, not the true efficiency explanation.[94] IDNs, in general, seem not to have been vehicles through which hospitals have asserted authority or developed pathways around traditional medical staff relationships to introduce cost-containment measures. "[I]ntegrated organizations have higher prices than stand-alone hospitals," with greater effects on exclusive arrangements and in less competitive markets.[95] In addition, at least in some studied areas, procedure rates seem to increase for hospitals with physician-hospital arrangements.[96] The result has been that expenditures in hospitals with physician-hospital organizations ("PHOs") were three percent higher than expenditures of patients in non-PHO hospitals.[97]

In a survey of evidence, Lawton Burns and Mark Pauly confirmed the conclusion that "affiliating or linking outpatient care with a large and complex inpatient institution tends to raise the marginal and average cost of both inpatient and outpatient care."[98] IDNs have not, in general, achieved a high level of clinical integration, which could lead to efficiencies and higher quality. Overall, Burns and Pauly are pessimistic about the future of IDNs, observing that "[t]he proportion of hospitals with these types of alliances peaked in 1996 and has declined ever since."[99]

What conclusion, if any, can be drawn from this brief survey of evidence? It seems that IDNs have not fulfilled at least one aspiration – more efficient and

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[91] *See, e.g.*, Federico Ciliberto & David Dranove, *The Effect of Physician-Hospital Affiliations on Hospital Prices in California*, 25 J. HEALTH ECON. 29, 37 (2006) (finding no evidence that vertical integration resulted in higher prices in California hospitals during the 1990s).

[92] Cuellar & Gertler, *supra* note 88, at 11.

[93] *Id.* at 26. The FTC and DOJ also expressed this concern in their joint report. *See* FED. TRADE COMM'N & DEP'T OF JUSTICE, *supra* note 90, at 13.

[94] *See, e.g.*, Alfredo G. Esposto, *Contractual Integration of Physician and Hospital Services*, 8 J. MGMT. & GOV'T 49 (2004) (concluding that cost-saving is not a basis for physician-hospital integration).

[95] Cuellar & Gertler, *supra* note 88, at 26.

[96] *See* Kristin Madison, *Hospital-Physician Affiliations and Patient Treatments, Expenditures, and Outcomes*, 39 HEALTH SERVS. RES. 257, 264-66 (2004) (studying certain cardiac procedures).

[97] *Id.* at 272.

[98] Lawton R. Burns & Mark V. Pauly, *Integrated Delivery Networks: A Detour on the Road to Integrated Health Care?*, HEALTH AFF., July/Aug. 2002, at 128, 130.

[99] *Id.*

lower cost delivery of medical care. It seems the objective that Mark Hall set out nearly twenty years ago – to change physician behavior and to reduce physician dominance[100] – has not (or at least has not yet) been achieved. But excessive pessimism also seems unwarranted. From a regulatory perspective, IDNs are not subject to the institutional or organizational rigidity of hospitals. Their organizational form can be flexible, driven by market realities, and unconstrained by the one-size-fits-all straitjacket of the hospital regulatory structure. This presents an opportunity for entrepreneurship and responsiveness to quality and cost challenges. IDNs have been and are likely to remain a battleground for the maintenance of physician control and dominance, in partnership with provider hospitals that apparently would rather combine than combat.

Hospitals have real and justified fears of alienating physicians, who are the caregivers and can influence patients. IDNs allow for flexible ordering of physician relationships with hospitals and other types of organizational forms. They may not have fulfilled the objectives that many set for them, and regulatory vigilance of their potential for anticompetitive effects is certainly appropriate. But they remain an important organizational form – a potential vehicle for accommodating marketplace demands for cost sensitivity and quality assurance. The flexibility that still characterizes the regulatory regime for IDNs is an important plus; the strategic goal is to develop incentives appropriately so that IDNs can be used constructively to improve performance in containing costs and improving quality.

VII. PHYSICIAN-HOSPITAL INTERACTION: THE FUTURE

Recent survey evidence indicates that hospitals are increasingly fearful of competition from physicians and concerned about threats to "long-standing collaborative relationships between physicians and hospitals."[101] This includes a concern by hospital administrators that competition between physicians and hospitals could "threaten physicians' long-standing orientation toward supporting hospitals' social missions, including caring for the uninsured."[102]

From the perspective of traditional community hospitals, physician-owned specialty hospitals and other facilities (such as laboratories) pose a competitive threat. According to a 2005 survey, this threat has increased from that per-

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[100] Hall, *Institutional Control of Physician Behavior*, *supra* note 22, at 507.

[101] Robert A. Berenson et al., *Hospital-Physician Relations: Cooperation, Competition, or Separation?*, 26 HEALTH AFF. w31, w32 (2007).

[102] *Id.* One surveyed hospital administrator expressed concern as follows:

> Doctors used to feel that in return for having the hospital as a place to care for their patients and earn income, they should contribute to the hospital, taking ED call, participating on committees, improving quality. Now they say to the hospital, screw you. . . . Many don't even come to the hospital any more.

Id.

ceived by hospital administrators in the previous 2000 survey.[103] This increasingly significant marketplace phenomenon has meant that hospitals face "growing competition" with physicians "over services that had once been within the hospital domain."[104] Many times the hospital is competing with its own medical staff, who are "opening an ambulatory surgery center [or] diagnostic center" and "shifting . . . services from hospital control to physician control."[105] This has led some surveyed hospital administrators to "consider[] the competition with physicians as actually more intense than with other hospitals in the community."[106]

This type of emerging competition between hospitals and physicians (including their own medical staff) highlights the point raised earlier – hospitals increasingly have their own independent institutional interests in the evolving health care marketplace. It reinforces the earlier critique of the traditional, rigid, one-size-fits-all regulatory regime of the modern American hospital. That traditional regulatory structure was a product of adherence to a vision – the professional/scientific paradigm – that no longer reflects the exclusive focus and function of the modern hospital. Hospitals are not merely workshops for physicians and do more than provide a forum or location in which physicians provide services to ignorant patients while the hospitals have no institutional interest in or accountability for what goes on within their four walls.

In response to growing physician competition, some hospitals will pursue cooperative or co-optative strategies, while others will seek to compete.[107] Cooperative or co-optative hospital strategies are often driven by a " 'half a loaf is better than none'" rationale.[108] Facing a potential loss of revenues to a free-standing (typically physician-owned) entity, some hospitals will form a joint venture with physicians in order "to retain some of the revenues they otherwise might lose."[109] This may be driven by the rationale "that the collaboration will help assure continued physician referral of patients who need inpatient hospital services."[110] In general, hospital officials view joint ventures of this type with physicians as "a way to reduce potential lost revenues from outmigration of services to physicians."[111]

Physicians are attracted to this type of joint venture with hospitals "because of their capital, their management experience, and the broader pool of patients that might be attracted."[112] Such joint ventures may also be a "way to

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[103] *Id.* at 33.
[104] *Id.* at 34.
[105] *Id.* at 35.
[106] *Id.*
[107] *Id.* at 37.
[108] *Id.* at 38.
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Id.*

avoid risky, head-on competition with the hospital."[113] Some physicians, however, have sought to partner with independent companies that will "contribute capital and management expertise to a joint venture with a physician group."[114] By forming a joint venture with an independent company, physicians are indeed engaging in direct competition with hospitals for services previously and historically provided by hospitals.

There is a concern that the legal regulatory regime may inhibit constructive cooperative arrangements. Relaxing restrictions on gainsharing might be an example of possible reform,[115] and the gainsharing demonstration should provide insight for consideration of regulatory reform in the anti-kickback and anti-self-referral arenas.[116]

Hospitals that might want to compete with (rather than cooperate with or co-opt) their staff physicians have traditionally faced an uncertain regulatory landscape. More recently (as described below), courts seem to recognize that hospitals have a legitimate interest in pursuing their own independent economic interests and have allowed hospitals to pursue policies designed to compete with physicians on their medical staffs.

The traditional hospital structure grants physicians control over medical staff competence through the credentialing process. The difficult issue arises when hospitals seek to incorporate criteria other than medical competence into the credentialing process. This is an understandable hospital response to competition from physicians, especially those on the hospital's medical staff.

As hospitals seek to compete on quality and price/cost, they seek greater control over decisions that affect their ability to manage quality and cost. Exclusive contracting with physicians or physician groups may be a way for hospitals to impose accountability for quality assurance on the medical staff, with a contractual means of enforcement. Similarly, a hospital may seek to impose conflict-of-interest rules which, in other economic sectors, would be deemed conventional protections against the inappropriate appropriation of corporate opportunity. Because physicians have significant influence on referrals, hospitals may reasonably fear that physicians will direct well-insured patients to their own facilities while referring underinsured or uninsured patients to the hospitals for service. In most other sectors, such self-defensive measures would be self-evidently rational and legitimate, but there has been tremendous controversy in the hospital sector over whether such economic credentialing is appropriate or legal.[117]

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[113] *Id.*

[114] *Id.* at 39.

[115] *See, e.g.*, Wilensky et al., *supra* note 41; *see also* MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO CONGRESS: PHYSICIAN-OWNED SPECIALTY HOSPITALS (2005), *available at* http://www.medpac.gov/publications_congressional_reports_Mar05_SpecHospitals.pdf. *See also* Saver, *supra* note 13.

[116] *See supra* note 14.

[117] For a recent consideration of these issues, see Cohen, *supra* note 53.

Recent court decisions seem to show receptivity to hospital claims in this arena. Courts appear more comfortable with hospital initiatives that focus on the institutional interest of the hospital itself. For example, in *Baptist Health v. Murphy*,[118] a private nonprofit hospital excluded physicians from the medical staff if they acquired or held an ownership or investment interest in a competing hospital. The Arkansas Supreme Court rejected a challenge to the hospital's action.[119]

Analogously, in *City of Cookeville v. Humphrey*, the Tennessee Supreme Court allowed a public hospital to "close" its imaging department by entering into an exclusive contract with a radiology group.[120] The hospital faced competition from a physician-owned imaging facility and was concerned about losing business to it. The physicians who owned the imaging facility were members of the medical staff at the public hospital. Notably, the court held that no hearing under the medical staff bylaws was necessary since the purpose of the hearing procedure was to determine medical competency, and the decision to close the imaging department was based on non-medical considerations.[121] The hospital's "decision to close the staff of the Imaging Department is a business decision," so a "due process hearing would be purposeless."[122] No hearing is required as an abstract matter, but is required if relevant facts that can lead to a finding of liability and a remedy are placed in controversy.[123]

In *Mahan v. Avera St. Luke's*, the South Dakota Supreme Court similarly allowed a hospital to close its staff for certain procedures.[124] The court held that the hospital's medical staff bylaws did not apply because the hospital decision in question was "not about appointments or the assignment or curtailment of privileges."[125] Instead, the decision was "about an administrative decision to close [the hospital's] staff for certain procedures," so the medical staff bylaws "do not apply."[126] The South Dakota court was expressly solicitous of the hospital's interest in establishing "clear lines of management authority" and worried about the "confusion" that would ensue if the hospital's lay board had only

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[118] Baptist Health v. Murphy, 2006 Ark. LEXIS 58 (Ark. 2006).

[119] *Id.* The Arkansas Supreme Court rejected a claim that the hospital's conduct violated the federal anti-kickback law. Had there been such a violation, the hospital's policy would have been invalid as a matter of public policy under state law. *See* Polk County v. Peters, 800 F. Supp. 1451, 1456 (D. Tex. 1992) (refusing to enforce a contract between a physician and a hospital in a claim for damages because the contract violated federal anti-kickback law and therefore was unenforceable under state law as against public policy).

[120] City of Cookeville v. Humphrey, 126 S.W.3d 897, 907 (Tenn. 2004).

[121] *Id.*

[122] *Id.*

[123] "[D]ue process protections are not triggered when the process would not serve any useful purpose or result in a remedy." *Id.* (citing Codd v. Velger, 429 U.S. 624, 627 (1977)).

[124] Mahan v. Avera St. Luke's, 621 N.W.2d 150, 163 (S.D. 2001).

[125] *Id.* at 157.

[126] *Id.*

a "minimal amount of control over its medical staff."[127]

In *Radiation Therapy Oncology, P.C. v. Providence Hospital*,[128] a private non-profit hospital's board of directors decided to establish an "integrated and unified cancer-care center where both radiation-oncology and medical-oncology services would be delivered to patients from one location."[129] This transfer resulted from the "poor" relationships between the radiation oncologists and the medical oncologists practicing at the hospital.[130] Accordingly, the hospital transferred its oncology program to an office-based practice group owned by the hospital's non-profit parent institution. The radiation oncology group that had practiced at the hospital contested the transfer, as they would no longer see radiation oncology patients at the hospital. The radiation oncology group claimed that the transfer "was unrelated to quality-of-care concerns" and therefore impermissible.[131] In rejecting this position, the Alabama Supreme Court held that the hospital's decision to transfer oncology services "did not violate the medical-staff bylaws" because the transfer decision was a "business decision[]" that the hospital was permitted to make under its corporate bylaws independent of the medical staff bylaws.[132]

These four recent cases suggest that courts are increasingly sympathetic to hospitals' assertion of their own independent institutional interests and that as a result credentialing on grounds other than medical competence is gaining judicial assent. This is an especially important and positive development in circumstances in which hospitals are seeking and exercising authority to better achieve institutional objectives such as quality assurance, accountability, and cost containment.

These recent cases also are suggestive of a broader set of legal and regulatory objectives.

First, the legal and regulatory environment should not have a large impact on how physician-hospital relationships should be mediated. The lack of a rigid regulatory structure for IDNs should be retained; the existing regulatory approach for hospital governance should not be transferred to the IDN setting.

Second, regulatory flexibility and regulatory neutrality should be the guiding objectives of public policy in this arena.

Third, the Gainsharing Demonstration should provide an occasion and a vehicle for initiating a comprehensive review of existing doctrines (e.g., anti-kickback and anti-self-referral laws) so that the focus of regulation is on inappropriate outcomes (such as anti-competitive conditions or poor quality results) but is crafted to permit innovative structures.[133]

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[127] *Id.* at 159.

[128] Radiation Therapy Oncology, P.C. v. Providence Hosp., 906 So.2d 904 (Ala. 2005).

[129] *Id.*

[130] *Id.* at 908.

[131] *Id.* at 909.

[132] *Id.* at 910-11.

[133] The enactment of the financial at-risk safe harbor under the anti-kickback law and the

Finally, constraining the rate of growth of costs is now more than ever a quality-of-care issue[134] and an access-to-care issue. Broader and more affordable coverage for medical care is directly linked to the cost of care.[135] The need to deal with cost-of-care issues suggests rethinking the regulatory structure of hospitals, allowing a more direct mechanism for incorporating cost factors into medical care decision making,[136] while at the same time maintaining regulatory flexibility for non-hospital organizational forms of physician-hospital relationships.

In sum, incorporating economic considerations into medical care decision making is a critical policy objective. Physician-hospital arrangements outside the traditional hospital governance structure still can act as important tools for achieving this alignment of interests, and as a result, encourage physicians to take costs into account in their decision making process. Their form and structure should not be locked into a one-size-fits-all framework, and they should not receive carte blanche when concerns about quality or competition exist. Because they remain relatively free of built-in regulatory obstacles to an appropriate structure, the varied organizational forms should remain available as new ways to create appropriate incentives for cost containment and quality assurance. As Robinson argued ten years ago, the appropriate organizational form should be seen as the "outcome of a competitive process in which particular forms survive" where they best perform the functions that need to be performed.[137] And, in a regulatory-neutral environment, public policy attention should turn to creating a system of competition that incentivizes the provision of good quality care and appropriately incorporates economic considerations

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binding advisory opinion process under the anti-kickback and anti-self-referral laws are examples of this type of approach. *See* HAVIGHURST ET AL., *supra* note 42, at 462-63, 495-96. In arrangements in which providers are financially at risk, for example, when managed care organizations receive capitated payments from Medicare, there is not a substantial risk of excess utilization, unlike the situation in which providers are paid on a fee-for-service basis. If there is a concern, it is with quality assurance not overutilization. *See* Timothy Stoltzfuss Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239 (1999) (raising concern about quality-of-care considerations in capitated settings). Use of financial inducements should be less subject to scrutiny on cost containment grounds in capitated situations. *See* Blumstein, *Speakeasy*, *supra* note 11. *See also* Blumstein & Sloan, *supra* note 9, at 78-82 (developing antitrust approach for specific contexts of antitrust risk).

[134] *See, e.g.*, Radiation Therapy Oncology, P.C. v. Providence Hosp., 906 So.2d 904, 915-16 (Ala. 2005) (Harwood, J., concurring) (noting that a quality of care concept is "broad enough" to encompass cost containment considerations).

[135] The State of Tennessee has recognized this in its reform of TennCare, the state's Medicaid demonstration. *See supra* note 24 (outlining the TennCare definition of medical necessity that expressly incorporates cost considerations into the determination of medical necessity, which defines the scope of a public TennCare beneficiary's entitlement to medical care services).

[136] *See* Blum, *supra* note 12; Hall, *Institutional Control of Physician Behavior*, *supra* note 22.

[137] Robinson, *supra* note 35 and accompanying text.

into the medical decision making process, while also providing appropriate disclosures to patients and involving patients in shared decision making.