Emerging Issues in Health Care Regulation: Protecting Patients or Punishing Providers

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EMERGING ISSUES IN HEALTH CARE REGULATION:
PROTECTING PATIENTS OR PUNISHING PROVIDERS?
A SYMPOSIUM INTRODUCTION AND OVERVIEW

Michele Mekel, J.D., M.H.A., MBA*

INTRODUCTION

No credible claim can assuage the assertion that medical errors beleaguer the health care industry and pose grave danger to patients.1 As with any issue that impacts both a significant segment of the population2 and a sizable component of the economy,3 the government has a vested interest. To that end, governmental forces, both state and federal, increasingly have turned toward the enactment of quality of care and patient protection regulation.4 Yet, such a command-and-control solution, although comparatively easy to institute, may not provide the optimal resolution. In fact, such top-down regulatory responses to health care quality and patient safety concerns may impose a number of deleterious effects, including increased health care costs, unanticipated conflicts with pre-existing regulation, and erosion of provider self-governance and innovative initiative, among others.

“[T]he overall value of a regulation … is a function of both the regulation's costs and its benefits—more precisely, a ratio of benefits to costs.”5 As to the cost aspect of the ratio, “the total societal cost of a regulation includes costs to the government, costs to consumers, and costs to the regulated entities.”6 An ambitious and first-of-its-kind effort to estimate the comprehensive value of health care regulation found that value to be a net cost of $169 billion as of 2002.7 Of that total, the study projected quality-related governmental oversight ran an estimated $51.6 billion8 but only returned an estimated benefit of $30.1 billion9—thereby contributing a projected $21.5 billion, or 13%, to the
overall net fiscal burden of health care regulation. Specifically with regard to determining the net cost of patient safety regulations, “the questions concern compliance costs in relation to benefits obtained, transaction costs associated with regulatory administration and enforcement, and unanticipated or unwanted responses on the part of the regulated industry.”

Additionally, “regulations may have high individual compliance costs, which are compounded by the fact[s] that[.] … organization[s are] simultaneously attempting to comply with other, possibly conflicting[,] regulations[,] … [and], when regulatory standards or mechanisms conflict …, they may prevent one another from achieving their intended benefit.” Such increasing legislative controls in highly complex, heavily regulated arenas—of which health care is one—merely lead to “regulatory inflation,” rather than enhanced compliance. Given that “a key determinant of government effectiveness is how well regulatory systems achieve their policy objectives,” compliance failures are a sign of ineffective regulation. Such systemic breakdowns: incur “unnecessary costs through fruitless administration and implementation”; delay or defeat “achievement of … policy objective[s]”; decrease “general confidence in the use of regulation, the rule of law, and government in general”; and undermine “other regulations and regulation itself, which can lead to a vicious cycle in which more and more rules are promulgated while public confidence in government regulation lessens and compliance outcomes become worse.” Moreover, the risks of compliance failures and regulatory inflation are heightened in the field of health care because jurisdiction is fragmented among federal, state, and local governments.

“Finally, ambiguous and complex regulations provoke feelings of regulatory overburden, including a sense of arbitrariness or unfairness in enforcement, which leads to decreased organizational energy for innovation and vigorous competition.” With regard to addressing patient safety and quality of care, such “functions are diffused through the system, and are[:] … essentially lodged with providers through professional licensing and accreditation agencies either constituted or recognized by the state; [or] … under the aegis of professional-state partnerships.” This type of bottom-up, private or quasi-private, provider-guided approach to quality of care and patient safety governance arises out of the fact that governments … face information gaps in regulating the behaviour of professional groups …. Accordingly, most systems for the regulation of health care professionals rely upon self-
regulation: placing the control of behaviour essentially in the hands of the professional group itself. In effect, this amounts to a “second-level” agency relationship between the state and the professional group.20

There are additional underpinnings for the reliance on self-regulation. These include: the “belief that industry-led approaches will create greater industry buy-in” in terms of adoption and compliance; the fact that “[s]elf-regulatory approaches may … reduce compliance and enforcement costs for the government”; and the perception that standards developed, enforced, and audited by third parties are both objective and credible.21

Yet, regardless of the potential injurious impacts of overzealous regulation, governmental stakeholders often instinctively turn to instituting such top-down mechanisms—typically in piecemeal fashion—when faced with both a problem of seemingly infinite complexity and political pressures to act quickly and affirmatively. “Regulation … frequently seem[s] advantageous because it is measured only against doing nothing, not against other promising policies that might have been but were not tried.”22 Reliance on a singular—and, oftentimes, inefficient—tool to resolve such multifaceted issues as patient safety and quality of care is, however, unlikely to yield a workable and effective governance model. This is because “regulatory intervention is [only] rational if it is cost effective—that is, if it is based on the best available evidence that the benefits of compliance outweigh [all of its] costs.”23

As a result, “[g]overnment should resist the temptation to micro-manage the [health care] system,” as “more will be achieved if [industry stakeholders] are given autonomy in how to reach those goals.”24 Perhaps, a palatable compromise approach would be so-called “responsive regulation,” of which “[t]he hallmarks … are flexibility in regulatory mandates and a collaborative relationship between the regulator and the regulated entity,”25 and in which regulators … outline an array of cost-effective potential interventions to improve quality and safety and give health care [providers] the opportunity to select from the menu and institute their own improvement programs. In this model, the role of the regulator is to ensure, through oversight of the process and periodic measurement of outcomes, that implementation and improvement are occurring.26

THE 2009 SIH/SIU HEALTH POLICY INSTITUTE

What is, and how to achieve, the ideal balance between providers and government, as well as other stakeholders, in the quality of care and patient safety domains were the questions addressed during the 2009 SIH/SIU Health Policy Institute (HPI). Held on May 15, 2009, at the Southern Illinois University School of Law in Carbondale, Illinois,
this HPI was cosponsored by Southern Illinois Healthcare and SIU’s Center for Health Law and Policy, as well as the Southern Illinois University School of Medicine Department of Medical Humanities.

Under the theme *Emerging Issues in Health Care Regulation: Protecting Patients or Punishing Providers?*, the 11th annual HPI featured the following speakers: Daniel H. Melvin, J.D., partner and member of the health law department of McDermott Will & Emery, L.L.P.; John A. Anderson, M.D., J.D., executive vice president of InoMedic, Inc., and former commander of Wright-Patterson Air Force Medical Center; Robert John Kane, J.D., assistant vice president and legal counsel for the Illinois State Medical Society (ISMS) and ISMIE Mutual Insurance Company; Patricia E. Sokol, J.D., senior policy analyst, clinical quality improvement and patient safety, American Medical Association; and John D. Blum, J.D., John J. Waldron Research Professor of Health Law at Loyola University-Chicago School of Law.

Sharing their astute insights, the presenters covered a panoply of issues at the nexus of patient safety and provider regulation—from the structuring of financial incentives to institutional oversight, and from regulatory compliance to emerging legal issues. This symposium issue of the *Journal of Legal Medicine* features articles by several of the HPI presenters, as well as a related piece by another legal scholar in the field.

The first article, *Patients as “Regulators”?: Patients’ Evolving Influence Over Health Care Delivery* by University of Pennsylvania School of Law Professor Kristin Madison, adeptly explores the idea that health care consumerism empowers individual patients to wield increasing control over health care providers, to alter the dynamics of patient-provider relationships, and, ultimately, to transform the health care system. As individuals move from the more passive role of patient to the more active role of health care consumer, she posits that such empowered patients become *de facto* regulators in that they can modify provider behavior through the exercise of market influence, rather than through legal authority. This new role of patient as *de facto* regulator, however, is not without peril; specifically, she cautions about patient-specific limitations, overarching system and information failures, and especially the erosion of physician
autonomy. Given these concerns, Professor Madison explores the range of potential provider responses to the patient-as-regulator trend and recommends that physicians adopt an active-engagement strategy.

In the second article, *The Quagmire of Hospital Governance: Finding Mission in a Revised Licensure Model*, Loyola-Chicago University Law Professor John Blum approaches health care regulation from the perspective of institutional governance and grapples with the evolving and expanding role of the hospital board. Professor Blum first offers an overview of the amalgam of legal principles that have converged to create the *de jure* foundations of hospital governance. He then touches upon recent events that have triggered renewed interest in governance, including “controversies over asset reallocation, concerns over the adequacy of non-profit hospital community benefits, and a new, expanded emphasis on hospital board oversight of clinical quality issues, including patient safety.” Asserting that the licensure scheme provides a regulatory center of gravity from which to direct the hospital governance function, Professor Blum argues for broad reform in this arena of legislative oversight. In so doing, Professor Blum looks to the evolving concept of “new governance,” “which applies to a series of theoretical and applied approaches to regulation” that establish “a middle ground between the more typical administrative law command-and-control models of oversight and self-regulation.” Building on a new governance approach, he then proposes a tripartite model by which to redesign hospital licensure, utilizing management-based and responsive regulation, and characterized by revamped baseline entry requirements, self-directed problem solving, and negotiated institutional obligations.

John Anderson, in *Evolution of the Health Care Quality Journey: From Cost Reduction to Facilitating Patient Safety*, examines the trajectory of the quality movement in health care, as well as Dr. Anderson's personal involvement with it. Observing the industrial adoption of Total Quality Management, based on W. Edwards Deming's philosophy of process improvement, the health care industry followed suit by implementing continuous quality improvement (CQI) programs, primarily to combat cost concerns. Anderson goes on to detail the progression of CQI in embracing patient safety in light of the recent Institute of Medicine's focus on medical error.
The fourth and final article, *Illinois Legal Developments Affecting Physicians and Hospitals*, by ISMS’s Robert John Kane, presents an update of recent case law and legislative changes. In addition, Mr. Kane provides a glimpse into legislative and regulatory issues that are on the horizon in Illinois with regard to health care.

**CONCLUSION**

The articles in this issue of the *Journal of Legal Medicine* consider different aspects of the appropriate roles for providers, the government, and other stakeholders to undertake in ongoing quality of care and patient safety improvement initiatives. Such pluralistic consideration is certain to inform and aid in determining how best to approach oversight of the complex issues inherent in health care quality and patient protection.

**Notes**

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2. See id.


Patient safety specifically refers to prevention of iatrogenic injury—that is, injuries caused by medical management as opposed to the patient's underlying disease process. Quality assurance aims more broadly at improving health outcomes by improving care processes, with an emphasis on basing medical decisions on the best available evidence and ensuring that patients receive needed services.
Mello et al., supra, at 377.

5. Mello et al., supra note 4.

6. Id. at 402.

7. CHRISTOPHER J. CONOVER, HEALTH CARE REGULATION: A $69 BILLION HIDDEN TAX 15 (2004) (see Table 5). This comprehensive net cost estimate was calculated in 2002 dollars based on a bottom-up analysis that rendered projected comprehensive costs of $339.2 billion and projected comprehensive benefits of $170.1 billion.

8. This was calculated by adding Conover's quality-related regulation cost estimates for health care facilities, providers, and health insurance. See id. at 6, 10, 11, 12, & 14 (especially Tables 2, 3, & 4). This cost calculation excludes those imposed by the medical malpractice system. See id. at 6, 10, & 15 (rendering estimated costs of the tort system at $113.7 billion in 2002 dollars).

9. This was calculated by adding Conover's quality-related regulation benefit estimates for health care facilities, providers, and health insurance. See id. at 6, 10, 11, 12, & 14 (especially Tables 2, 3, & 4). This benefit calculation excludes those garnered from the medical malpractice system. See id. at 6, 10, & 15 (resulting in estimated benefits from the tort system of $33 billion in 2002 dollars).

10. This was calculated by subtracting Conover's quality-related regulation benefit estimates for health care facilities, providers, and health insurance from his quality-related regulation cost estimates for the same. See id. at 6, 10, 11, 12, & 14 (especially Tables 2, 3, & 4). This net cost calculation excludes those estimated costs and benefits arising from the medical malpractice system. See id. at 6, 10, & 15 (resulting in projected net costs of $80.6 billion in 2002 dollars from the tort system).

11. Mello et al., supra note 4, at 398. See generally id. at 398-403 (discussing the overarching types of costs and their effects).

12. Id. at 402.


15. Mello et al., supra note 4, at 387.


17. Mello et al., supra note 4, at 402.


19. Bottom-up mechanisms share the commonality of being instigated by individuals or entities in the private sector. See Mello et al., supra note 4, at 387. Other bottom-up approaches include medical malpractice and health care consumerism. See id. at 377 & 381. In fact, medical malpractice litigation “has served as the primary form of patient safety regulation.” Id. at 387-92 & 411-13 (noting that the efficacy of civil tort actions has been called into question and discussing some of the concerns).

20. Tuohy, supra note 18, at 22-23. This is not to assert, however, that self-regulation is an infallible panacea. Self-regulation can be exploited to subvert government oversight, evade or obscure public accountability by industry participants, and serve as the ceiling—rather than the floor—for performance. Id. This also should not be viewed as an argument that all quality-control functions should be removed from state oversight.
21. ELIADIS, supra note 13. An example of the success of such quasi-private, provider-guided oversight was highlighted in a study finding that a professional, quasi-regulatory body—The Joint Commission—has had the greatest impact, bar none, on United States hospitals' patient-safety efforts to date. Kelly J. Devers et al., What Is Driving Hospitals' Patient-Safety Efforts?, 23 HEALTH AFF. 103 (2004) (also discussing other entities that impact, to a much lesser extent, American hospitals' patient safety efforts, factors that facilitate patient safety at the organizational level, and barriers to patient safety implementation). See generally Mello et al., supra note 4, at 382 (discussing The Joint Commission's patient safety initiatives).


23. Mello et al., supra note 4, at 376.


25. Mello et al., supra note 4, at 414.

26. Id.


28. Id. at 10-21.

29. Id. at 21-23.

30. Id. at 23.

31. Id. at 23-24.

32. Id. at 24-27.

33. Id. at 28-31.

34. Id. at 31-32.


36. Id. at 36-41.

37. Id. at 41.

38. Id. at 51-56.

39. Id. at 54.

40. Blum describes management-based regulation as “oriented around planning” by “regulated entities[, which] develop and comply with their own constructed solutions to particular problems.” Id. at 55.

41. See supra notes 25 & 26 and accompanying text.

43. *Id.* at 64-65.

44. *Id.* at 68-70.


46. *Id.* at 79-89.