COMBATING THOSE UGLY MEDICAL ERRORS – IT'S TIME FOR A HOSPITAL REGULATORY MAKEOVER!

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"The good government employs peaceful means of regulation"

Lao Tzu

I. INTRODUCTION

By and large the portrait of American health care in the early 21st century is one that captures an image of a system characterized by contrasts and contradictions. On one side of the picture, American health care is represented by an image depicting extensive and impressive technological capabilities where, for example, a procedure such as a coronary artery bypass is seen as routine.[1] While on the other side of the same portrait, health care presents an enterprise in crisis, reeling from ongoing challenges, and always desperately in search of solutions to its myriad of challenges. The fact is that any broad representation of the American health system is likely to be multi-colored, layered with numerous contrasts, and ultimately any attempt to capture an overall image of this system will be highly subjective, either framed by personal experiences, or too often shaped by the collective power of anecdotes.[2] The portrait of health delivery in the ranks of the insured public, while no longer a Norman Rockwell image, will reflect moderate contentment; but to the forty-five million without health insurance, the portrait of the American health system will be one drawn in a stark manner.[3] In the provider community the picture of the health system will be a dark one, reflecting deep concerns, particularly on the part of physicians as they cope with pressures to "do more with less," and experience an ongoing erosion of professional autonomy.[4] The most negative in the ranks of organized medicine may depict the American health system in a manner akin to Edward Munch's painting "The Scream," but even the more hopeful in the provider world are likely to portray the health delivery system with a negative cast.[5] The image of the system drawn by those in the world of health policy will be even darker, more akin to a Jackson Pollock painting where continual and emerging

1. *See* Richard Pérez-Pena, *For Clinton's Lead Surgeon, Little More Than a Day's Work*, N.Y. TIMES, Sept. 7, 2004, at A18.

2. *See* David A. Hyman, *Patient Dumping and EMTALA: Past Imperfect/Future Shock*, 8 HEALTH MATRIX 29, 33-44 (1998).

3. *See e.g.*, *Health Care Choice Act: Hearing on H.R. 2355 Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 109th Cong. 14-15 (2005) (statement of Merrill Matthews, Dir., Council for Affordable Health Insurance).

4. James L. Reinertsen, *Zen and the Art of Physician Autonomy Maintenance*, 138 ANNALS INTERNAL MED. 992, 992 (2003).

5. *See* J. P. HODIN, EDVARD MUNCH (Thames & Hudson, photo reprint 1993) (1972).

problems of cost, quality, and access are spread across the canvas of health care appearing random, chaotic, and multi-layered, both incredibly difficult to understand, and even more difficult to resolve.[6]

This essay stems from a Jackson Pollock-like vision of our health system, as it is centered on the current crisis to engulf the canvas of American health care: that of medical errors. Since the now landmark study of the Institute of Medicine, *To Err is Human*, there has been a growing awareness of, and focus on, hospital-based medical errors, both to understand the scope and nature of the error problem, as well as to develop solutions, at the conceptual and operational levels.[7] Although great progress is being made in hospital error prevention, the issue continues to evolve, fueled by studies that reveal even more pervasive problems in the area.[8] The medical error crisis is part of an evolving picture; new revelations of injury and death caused by preventable mistakes strike and run in unpredictable ways across the canvas of health care.

While this piece is sparked by the evolving, somewhat chaotic image of medical errors, it is not written to posit a specific solution to this profound challenge, but, rather, focuses on how regulatory law can be made more effective in addressing the various problems that fall within the context of medical errors. This article is further removed from the front-line of medical error issues in that it does not make a specific recommendation for a given regulatory solution, but, rather considers how a new model of regulation might be better utilized as a tool to address the medical error problem.

It is the premise of this essay that health regulation, in the context of hospitals, is a matter of tradition, convenience, and political expediency, but is rarely thought of as a distinct tool that, in and of itself, offers the potential for facilitating solutions to given problems. This piece will make the argument that the current regulatory approaches applied in the hospital world, and seen in responses to medical errors, should be reevaluated, and that new models of regulation should be explored as tools to enhance patient safety. Specifically, this essay will examine broadly the types of regulations found in the hospital sector, demonstrating the scope of this enterprise in the acute care setting, and highlighting the various regulatory models that are being used in this sector. Secondly, the paper will consider current and proposed regulatory initiatives, focusing on the battles against hospital-based medical errors that have been pursued at the federal and state levels, as well as in the private sector. The third section of the paper will focus on how the regulatory landscape affecting hospitals can be reshaped, and how a new approach to regulation could facilitate

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6. *See* ELLEN G. LANDAU, JACKSON POLLACK (1989).

7. INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM 1 (Linda T. Kohn et al. eds., 2000).

8. HEALTH GRADES, HEALTH GRADES QUALITY STUDY: PATIENT SAFETY IN AMERICAN HOSPITALS (2004), http://www.healthgrades.com/media/english/pdf/HG_Patient_Safety_Study _Final.pdf.

better solutions to the hospital medical error crisis. A new model for dealing with medical errors will be taken from a developing regulatory model. Management-based regulation will be posited and two approaches to this model will be considered: one building off of the Centers for Medicare and Medicaid Studies ("CMS") Quality Assessment and Performance Improvement ("QAPI") program, and the other entailing adoption of a multi-industry quality model, ISO 9000.[9]

II. The Landscape of Hospital Regulation

The acute care hospital has the ubiquitous distinction of being one of the most heavily regulated entities in American society.[10] Hospitals face a wide and complex array of broad and narrow mandates emanating from all levels of government, as well as from the private sector. Being the focal point of our health delivery system, acute care facilities have been, and likely will continue to be, subjected to increased regulatory pressures, reflecting complex and often contradictory public goals.[11] Expanding operational and financial complexities have sparked growth in hospital regulation, along with governmental responses to highly publicized health care problem areas like access, privacy of medical information, charity care obligations, and medical errors.[12] Issue-oriented regulation is driven by politics and frequently results in the proliferation of mandates that are layered onto existing obligations, often uncoordinated with established regulatory requirements.[13]

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9. Conditions of Participation for Hospitals, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified as 42 C.F.R. pt. 482).

10. AM. HOSP. ASS'N TASKFORCE ON REGULATORY RELIEF & REFORM, FINAL REPORT, APP. E, Hospital Regulation (2002) [hereinafter AHA TASKFORCE].

11. The American Hospital Association Taskforce on Regulatory Relief and Reform is based on the premise that hospitals are over regulated. In July 2004, the Department of Justice and the Federal Trade Commission issued a report on Competition and Health Care, *see* DEPT. OF JUSTICE, DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION ISSUE REPORT ON COMPETITION AND HEALTH CARE (2004)*,* http://www.usdoj.gov/atr/public/press_releases/2004/204711.htm. The report focused on antitrust law but is reflective of the ongoing struggles in health care seen in the hospital sector, between regulation and free market competition. In the process of preparing the report, the FTC/DOJ held various hearings. In one of the hearings, Eugene Anthony Fay, the Vice President of Government Affairs of Province Healthcare Company, testified on behalf of the Federation of American Hospitals. Mr. Fay pointed out in his remarks the scope of federal and state regulation confronted by hospitals. FEDERATION AND AMERICAN HOSPITALS, FTC/DOJ HEARINGS ON HEALTH CARE AND COMPETITION LAW AND POLICY STATEMENT OF THE FEDERATION OF AMERICAN HOSPITALS (2003), http://www.FTC.gov/ogc/healthcarehearings/ docs/030410Fay.pdf.

12. AHA TASKFORCE, *supra* note 10.

13. *Id.*

A. Scope of Hospital Regulation: A Simple Scheme

While there are many ways to characterize hospital regulations, the scope of this enterprise can be demonstrated by means of a simple four fold classification: core regulation, institution-wide regulation, targeted regulation, and private regulation. Core regulation entails fundamental institution-wide mandates that establish basic structure and operating processes which must be met for a facility to function. The best example of core regulation is found in state hospital licensure laws, which form a type of baseline that serves as a gateway into the regulated activity.[14] The licensure baseline is not static, but is frequently altered in response to changes in the enterprise and the needs of the public. Institution-wide regulations, while not entry regulations, have ramifications throughout the entire facility. A prime example of an institution-wide mandate can be found in the reimbursement area, in particular in Medicare, where participation in the program requires meeting extensive Conditions of Participation requirements that touch on all facets of a hospital operation.[15] Some institution-wide mandates, such as the relatively recent federal rules in the area of medical privacy,[16] may be less pervasive than Medicare requirements, but are felt, nevertheless throughout the hospital. The third generic category of regulation, targeted regulations, impacts a particular area of the hospital operation, whether that be a given unit or service area, or a particular hospital function. In some instances, targeted regulations may have broad impacts on the operation such as the federal and state requirements to provide emergency medical services, and, in other cases, regulations may be very narrow and focused on a very discrete aspect of the operation.[17] While technically private regulation, or voluntary regulation, lacks the legal status of the other generic regulations noted, this type of regulation is very significant in the hospital sector. In particular, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") has developed industry standards which are widely subscribed to, as the voluntary JCAHO requirements act as a mechanism for hospitals to qualify for Medicare participation.[18]

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14. *See* DEL. CODE ANN. tit. 16, § 1005 (2003), HAW. REV. STAT. § 321-14.5 (2004), 210 ILL. COMP. STAT. ANN. 85/6 (West 2000), MINN. STAT. ANN. § 144.50 (West 1998).

15. *See* 42 C.F.R. §§ 482.1-482.66 (2004).

16. *See* 45 C.F.R. §§ 164.306-.534 (2005).

17. *See* Emergency Medical Treatment and Active Labor Act, 42 U.S.C. §1395dd (2000) for the requirements which have grown over the years. On the other hand, there are many narrower requirements, often contained in licensure laws, such as the California directive that patients be given written information about their rights upon admission, CAL. HEALTH & SAFETY CODE § 1262.6(a) (West 2002), and the New York law mandating a patient safety center, N.Y. PUB. HEALTH LAW § 2998 (McKinney 2000).

18. *See* Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?*, 57 LAW & CONTEMP. PROBS. 47, 52-55 (1994). For information on JCAHO, *see* Joint Commission on Accreditation of Healthcare Organizations

Undoubtedly the scope of hospital regulations is broad, and will continue to be a contentious area for the industry. Appreciating the breadth of hospital regulation is significant in that it should give pause to government officials designing strategies to meet ongoing and emerging problems through additional regulation. The matter of regulation is not, however, merely a question of volume, but ultimately a matter of effectiveness. The fact that there are numerous regulations impacting hospitals, in and of itself, means little, and certainly extensive regulation can be expected in fields that are highly complex and imbued with strong public purpose. The difficulty with hospital regulation, especially in the context of this article, is that the effectiveness of this extensive body of mandates must be called into question in light of the profound problems concerning hospital-based medical errors that have emerged and continue to unfold.

B. *Types of Regulation*

Prior to the exploration of the relationship between medical errors and hospital regulation, it is necessary to address not only the volume of hospital regulation, but also the types of regulation being applied. The American Hospital Association has identified seven regulatory models used in the hospital arena: command and control regulation, public utility regulation, inspection, reporting and disclosure, performance-based regulation, delegated regulation, and market-based regulation.[19] All of the models noted by the American Hospital Association ("AHA") have been employed to varying degrees in the hospital sector, both by accident and by design. Undoubtedly the most prevalent model of hospital regulation is the command and control one, which emanates from the rule-making process of administrative law.[20] Both public health insurance programs at the state and federal levels, as well as licensing agencies use a command and control approach, and the largest volume of hospital regulation dealing with the delivery of services, benefits and payment issues falls into this category. More recently, the rule-making process has been used as a way to implement new policies that are stymied in the legislative branch.[21] The public utility model, which typically is a mechanism to regulate rates and service areas, has been used in a limited fashion in the hospital world, and can be seen as a throwback to an era in which regulators felt costs could be controlled through strong government oversight.[22] In some jurisdictions, hospitals were subjected

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(2005), http://www.jcaho.org/about+us/. The deemed status attached to JCAHO accreditation can be found at 42 U.S.C. § 1395bb (2001), 42 C.F.R. § 4885 (1993).

19. AHA TASKFORCE, *supra* note 10, at App. E.

20. *Id.* at 3-5.

21. *Politics & Policy Federal Regulations: NYT Examines Aggressive Use by Bush*, AM. HEALTH LINE, Aug. 16, 2004.

22. AHA TASKFORCE, *supra* note 10, at 1-3.

to rate-setting authorities and more commonly the creation and expansion of hospital services has been controlled through state certificate-of-need legislation.[23]

The use of inspection as a regulatory tool is common to hospitals and other health facilities as a mechanism to control entry and to ensure ongoing compliance with established or expanded mandates, generally through licensing processes or private sector certification.[24] In addition, inspection regulations often contain provisions which allow regulatory follow-up based on consumer complaints.[25] A regulatory model of particular relevance to the topic at hand, medical errors, is the process of reporting and disclosure, which has its roots in a consumer-oriented view of regulation that places strong faith in the use of data to both identify and spark solutions to problems.[26] Reporting requirements affecting hospitals have been prevalent for some time in a variety of contexts, but in the emerging crisis of medical errors there is a widespread acceptance of reporting as a mechanism to both identify and control error issues.[27]

A very recent regulatory model in health care, being considered for use in the hospital sector by the CMS, is the use of performance-based regulation.[28] Performance-based regulation recognizes the achievement of established outcomes as the key goal of regulation, and rewards entities that meet or exceed targets. Under the auspices of CMS, demonstration projects are being developed to reimburse hospitals at higher levels, based upon performance.[29] The so-called pay-for-performance initiatives are being widely investigated by the public and private sectors alike, as a mechanism to reward optimal performance and allow regulators to focus on institutions whose performance falls below standards.[30] Delegation emerged as a mechanism to augment government oversight and, to

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23. *See* Christopher J. Conover & Frank A. Sloan, *Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?*, 23 J. HEALTH POL. POL'Y & L. 455, 455 (1998).

24. *See* Illinois Hospital Licensing Act, 210 ILL. COMP. STAT. 85/1-16 (West 2005).

25. *See* FLA. STAT. ANN. § 395.0161 (West 2002).

26. AHA TASKFORCE, *supra* note 10, at 4.

27. Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 HOUS. J. HEALTH L. & POL'Y 181, 203-06 (2003); Melissa Chiang, *Promoting Patient Safety: Creating a Workable Reporting System*, 18 YALE J. ON REG. 383, 383 (2001); Bryan A. Liang, *The Adverse Event of Unaddressed Medical Error: Identifying and Filling in the Holes in the Health-Care and Legal Systems*, 29 J.L. MED. & ETHICS 346, 357-358 (2001).

28. *See* Premier, *Groundbreaking Pay for Performance Project Reports Quality of Care Improvement at Participating Hospitals*, http://www.premierinc.com/all/newsroom/press-releases/05-may/pay-for-performance.jsp (last visited Feb. 11, 2006).

29. *Id.*

30. *See* L. Gregory Pawlson, *Pay for Performance: Two Critical Steps Needed to Achieve a Successful Program*, AM. J. MANAGED CARE, Nov. 2004, at 4 (Supp. III); Price Waterhouse Coopers, *Pay for Performance's Small Steps of Progress* (2004), http://www.pwchealth.com/cgi-local /hcregister.cgi?link =pdf/p4p.pdf. *See also* National Quality Forum, *Pay for Performance: Guiding Principles and Design Strategies* (2004).http://www.qualityforum.org/txNQFproject Summaryp4p12-20-04.pdf.

an extent, addresses the inability of government to protect the public in highly technical areas. Delegated regulation, as previously noted, plays a very significant role in the hospital world, as Medicare has transferred authority to a private entity, JCAHO, to determine whether a given institution meets the necessary requirements for participation in the federal health program.[31] Finally, market regulation is a type of de facto regulatory model in that government relies on the hospital marketplace to provide health care in a competitive setting, and it is the market that becomes the determinant of services and pricing.[32] In the event hospitals behave in an anticompetitive fashion, causing a breakdown in the market, government, under the auspices of the antitrust laws, may chose to intervene to correct abuses.

While application of a given regulatory model may be a deliberate choice, it is not always clear whether such a choice is a matter of expediency, tradition or is reflective of a carefully thought-out strategy. In the abstract it is difficult to make value judgments about the appropriateness of a given regulatory model. Divorced from ideological biases, the evaluation of the efficacy of a given approach to regulation comes down to a matter of determining whether a particular regulation meets its stated goals and reflects a compatibility with the industry it is designed to control. It seems clear that no one model of regulation is adequate for the hospital sector, but rather, complexities in this area require a variety of approaches.[33] It also seems clear that the current models of regulation need to be continually evaluated and that emerging problems, such as medical errors, should be seen as ones that continually force assessment of regulatory models. The AHA Taskforce on Regulation has recommended that new models of regulation be developed in light of its perceptions concerning the shortcomings and burdens of established government approaches to regulating the hospital sector.[34] The AHA cautioned that exploration of new regulatory models for hospitals needs to be measured against fiscal realities, and even more broadly, must be guided by a sense on the part of regulators as to whether hospitals exist as a commodity or public good.[35] Additionally, considering new regulatory models, the underlying questions that must be confronted are whether there will be a willingness on the part of regulator and regulatee to accept new regulatory formats, and more broadly, whether a given format is a viable way of enhancing the public's health.

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31. 42 C.F.R.. § 488.6 (2006).

32. AHA TASKFORCE, *supra* note 10, at 4.

33. *Id.* at 4-5.

34. *Id.* at 5.

35. INSTITUTE OF MEDICINE, *supra* note 7, at Executive Summary.

III. THE CONTEXT

Before positing an alternative regulatory model, it is first necessary to explore the context within which that model would be applied, namely hospital-based medical errors. In 1999 the Institute of Medicine ("IOM") issued its now well-known report, *To Err is Human*, in which it concluded that between 44,000 to 98,000 patients died in American hospitals as a result of preventable medical errors.[36] The IOM Report set the stage for a major initiative in American health policy directed at preventing medical errors and enhancing patient safety.[37] All aspects of health care delivery, medical, surgical, and pharmaceutical, in inpatient and ambulatory settings, have had to confront the growing awareness of medical errors and implement changes to enhance patient safety. The epicenter of the patient safety movement has been the acute care hospital, where an array of clinical and operational efforts are ongoing to reduce medical errors.[38]

Medical errors still pose a major challenge for acute care facilities; even with changes in patient care processes, recent studies have indicated that problems in this area may be more significant than what was revealed in the 1999 IOM study.[39] A report on medical errors issued in 2004 by the consulting group Health Grades estimated that the annual hospital patient deaths attributable to errors were over 200,000.[40] The Health Report study was based on sixteen patient safety indicators developed by the U.S. Agency for Healthcare Research and Quality ("AHRQ"), and almost seventy-five percent of the estimated deaths in the study resulted from the application of a new patient safety standard, "the failure-to-rescue."[41] Use of new safety indicators will likely expand the rates of medical errors, as well as fuel the ongoing awareness of how widespread problems in the area are. A noted health services researcher reported in 2003 that 100 patients will die daily in U.S. hospitals as a result of preventable errors, and another patient safety expert lamented that even five years after the first IOM Report, serious problems in patient safety still existed.[42]

Not all the news on the patient safety front is negative and the IOM report and its progeny has served as a catalyst for a wide range of activities geared

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36. IOM*, supra* note 7*,* at 1.

37. Furrow, *supra* note 27, at 203.

38. *See* John P. Marren, G. Landon Feazell & Michael W. Paddock, *The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions*, 12 ANNALS HEALTH L. 179 (2003).

39. *See* HEALTH GRADES, *supra* note 8, at 6.

40. *Id.* at 3.

41. *See id.* at 4; John Morrissey, *Error Measure Draws Critics*, MODERN HEALTHCARE, Aug. 2, 2004, at 12.

42. Donald M. Berwick, *Errors Today and Errors Tomorrow*, 348 NEW ENG. J. MED. 2570, 2570 (2003); John Morrissey, *Patient Safety Proves Elusive: Five Years After the Publication of the IOM's "To Err is Human," There's Plenty of Activity on Patient Safety, but Progress Is Another Matter*, MODERN HEALTHCARE, Nov. 1, 2004, at 6 (comments of Brent James).

toward addressing various facets of the medical error issue.[43] Responses to medical error problems encompass activities to identify and assess medical errors, establish new operational policies and standards, as well as the development of governmental policies, which include the creation of various legal mandates. There are numerous public and private initiatives, which are focused on identifying and assessing medical errors and developing strategies to prevent future problems. Typical operational responses at the hospital level include developing better management information systems to address problems in medication errors, and particular emphasis has been placed on infection control, equipment errors, and even routine slip and fall issues.[44] New IT systems address long-standing problem areas such as tracking patients in the emergency room and providing more timely results of diagnostic testing.[45] Hospitals are also cautioning patients about safety issues and stressing the need for better communications between staff and patients.[46] A not-for-profit organization, the National Quality Forum ("NQF") endorsed twenty-seven safety practices that should be used in applicable clinical settings to reduce the risk of harm to patients.[47] The NQF safety practices include use of eleven recommendations for specific clinical care processes, seven recommendations for information transfer and communications, and additionally incorporated prior recommendations for use of physician computer order entry systems ("CPOE"), ICU physician staffing levels, as well as evidence-based referrals for high risk procedures.[48] A related private sector entity, the Leapfrog Group, recently surveyed 1,000 hospitals concerning awareness, accountability, and action in thirty safety areas, using the twenty-seven areas identified by the NQF.[49] The Leapfrog survey indicated that hospitals are taking steps to improve patient safety such as developing procedures to prevent wrong site surgery, or requiring pharmacists to review medication orders before administration to patients. On the other hand, the survey revealed failures in a number of areas, such as

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43. *See* Morrisey, *supra* note 42.

44. For examples of patient safety approaches at one hospital *see* Central Maine Medical Center, *Patient Safety Quality Management Report*, http://www.cmmc.org/qualityreports/patient _safety.html (last visited July 3, 2005).

45. *See* John Morrissey, *Move Over HIPAA: Patient Safety Emerges as No. 1 Safety Priority for IT Pros*, MODERN HEALTHCARE, Feb. 17, 2003, at 14.

46. *See* Yale-New Haven Hospital, *Patient Safety: Staying Safe in the Hospital*, http://www.ynhh. org/choice/safety.html (last visited June 30, 2005) (encouraging communications between the patient and healthcare professional as a fundamental aid to safety).

47. *See* THE NATIONAL QUALITY FORUM, *SAFE PRACTICES FOR BETTER HEALTHCARE*: A NATIONAL QUALITY FORUM CONSENSUS REPORT (2003), http://www.qualityforum.org/safe_ practices_report.html (access by clicking on various chapters).

48. *Id.*

49. THE LEAPFROG GROUP, THE LEAPFROG GROUP HOSPITAL QUALITY AND SAFETY SURVEY (2004), http://leapfrog.medstat.com/pdf/faq.pdf.

requiring workers to wash their hands with disinfectant before and after seeing patients, or having procedures in place to prevent bed sores.[50]

A. Federal Responses

The federal regulatory response to the problem of medical errors has been shaped by the recommendations of the Institute of Medicine that call for action to address the problem generally, implementation of a system of public accountability, development of a knowledge base regarding medical errors, and promotion of a cultural change to reduce errors and improve patient safety.[51] On the non-regulatory side, the AHRQ has taken the lead in coordinating research and consultation in the area of medical errors.[52] Under the auspices of its Patient Safety Initiative, AHRQ has developed a long-term plan which includes the following: pinpointing threats to patient safety; identifying and evaluating effective patient safety practices; teaching, disseminating, and implementing effective patient safety practices; and engaging in ongoing monitoring in the area.[53] The AHRQ conducts much of its work in conjunction with the private sector through grants and contracts. The Agency commissioned a systematic exploration of patient safety practices, which entailed review of seventy-nine practices, which has in turn served as a baseline for individual hospital evaluations.[54] Recently, AHRQ released a new tool to help hospitals and health systems evaluate employee attitudes about patient safety in their facilities: the Hospital Survey on Patient Safety Culture.[55]

In the regulatory context, the concern over medical errors and the goal of enhancing patient safety is beginning to have direct and indirect impacts on Medicare policies, as well as on policies of other agencies such as the Veteran's Administration. The Centers for Medicare and Medicaid Services issued a final rule requiring hospitals to develop and maintain, as noted, what is referred to as a Quality Assessment Performance and Improvement program ("QAPI"), which is a part of the broader Medicare Conditions of Participation ("COP").[56] QAPI

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50. *See* LEAPFROG GROUP, *supra* note 49.

51. *See* IOM, *supra* note 7, at 3-4.

52. *See generally*, AHRQ, Medical Errors & Patient Safety, http://www.ahrq.gov/qual/errorsix.htm (last visited Nov. 1, 2005).

53. AHRQ, *AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risks*, http://www.ahrqgov/qual/pscongrpt (last visited Nov 1, 2005).

54. AHRQ, *Making Healthcare Safer: A Critical Analysis of Patient Safety Practices: Summary*, http://www.ahrqgov/clinic/ptsafety/summary.htm (last visited Nov. 1, 2005).

55. The survey was designed in partnership with a hospital group, Premier Inc., the U.S. Department of Defense, and the American Hospital Association, and is designed to measure conditions that can lead to adverse events and patient harm. *See* AHRQ, *Hospital Survey on Patient Safety Culture*, http://www.ahrq.gov/qual/hospculture/ (last visited Nov. 1, 2005).

56. Conditions of Participation for Hospitals: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified 42 C.F.R. 482.21).

is a minimum requirement that calls for hospitals to systematically examine their quality and develop improvement projects on an ongoing basis.[57] Central to this regulatory regime are the goals of demonstrating both measurable progress in quality through improved health care outcomes and quantifiable reductions in medical errors.[58]

CMS casts the net of medical errors quite broadly, beyond medication and surgical errors, and includes harm experienced while receiving health care such as diagnostic errors, equipment failures, infection, blood transfusion-related injuries, and deaths due to seclusion or restraint.[59] Specifically, the QAPI program entails four sets of requirements: first, the development of an ongoing, hospital-wide program that measures reductions in medical errors; second, a clearly defined policy on supporting data; third, a priority-setting process for improvements which tracks and analyzes adverse patient events and implements preventive actions; and fourth, the implementation of quality improvement projects proportional to the scope and complexity of hospital services.[60] What is particularly noteworthy about the QAPI requirements is that considerable discretion is placed into the hands of the individual hospital to design a program which fits its particular needs and, as such, reflects a concerted effort by the regulators to move away from a heavily prescriptive approach to dealing with hospital-based medical errors.

CMS in its final rule backed away from a proposed requirement that hospitals assess their performances in twelve specific areas.[61] Although flexible, the QAPI regulations are not totally opened-ended in that compliance is to be measured by state agency surveyors, who will evaluate the hospital-wide effectiveness of a given program, so that institutions significantly out of compliance can be terminated from the Medicare or Medicaid programs.[62] While CMS pledges to harmonize its quality evaluation measures with the Joint Commission on Accreditation of Hospitals, the JCAHO accreditation that allows entrance into Medicare and Medicaid via deemed status will not replace an independent state agency evaluation of individual QAPI programs.[63]

The medical error issue has also influenced Medicare policies in a more indirect fashion. For example, the state-based Medicare Quality Improvement Organization ("QIO") is involved directly in specific and related medical safety efforts. In their current contract cycle, the QIOs have been charged specifically with working with rural hospitals in developing an organizational culture of

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57. *Id.*

58. *Id.*

59. *Id.* at 3435-36.

60. *Id.* at 3449.

61. Conditions of Participation for Hospitals: Quality Assessment and Performance Improvement, 68 Fed. Reg. at 3438-39.

62. *See id.* at 3442-43.

63. *Id.* at 3450.

safety.[64] More generally, the QIOs, as Medicare's quality assurance arms, have been mandated to improve hospital performance in various clinical areas such as surgical complications, colorectal cancer screening, and pressure ulcers. These quality improvements have clear implications for error reduction and patient safety.[65] One current QIO target includes workforce turnover, a problem in health care institutions that has a very strong and well-established tie to patient safety.[66]

The QIOs are also mandated under the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") with collecting acute care institutional performance data and providing hospitals with consultation in meeting the new data reporting mandate.[67] Prior to the 2003 Medicare legislation, nearly 4,000 hospitals voluntarily reported performance data to CMS in targeted areas.[68] Under the MMA, most hospitals are required to submit performance data to QIOs in ten target areas dealing with practices concerning heart attacks, heart failure, and pneumonia.[69] The submitted data will create a national information repository that will allow for comparative analyses of hospital performance in the respective areas. The results of the reporting initiative will be available to consumers and should be a catalyst for improvement in the affected areas, resulting in better performance and as such, prevention of medical errors. Hospitals that fail to report quality measures in the specified areas will receive a 0.4% lower Medicare payment update than reporting entities.[70] In a small way the new reporting mandate is CMS' initial venture into pay-for-performance regulation. Although the reporting mandate only penalizes the failure to comply, presumably the next possible phase of such regulation will be to reward those acute care entities whose performance in the reported areas exceeds certain thresholds.

Within other federal health programs, patient safety has become a priority area as well. The Veterans Administration ("VA") has been very active in the patient safety area. Even prior to the IOM Report, the VA developed the National Center for Patient Safety, which coordinates system-wide efforts, and individual

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    64. OFFICE OF CLINICAL STANDARDS & QUALITY, QUALITY IMPROVEMENT GROUP, CENTERS FOR MEDICARE & MEDICAID SERVICES, PROPOSED SUMMARY OF DRAFT 8TH STATEMENT OF WORK 8 (2004).

    65. *Id.* at 2.

    66. *Id.*

    67. Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, § 109, 117 Stat. 2006 (2003).

    68. Ctrs. for Medicare & Medicaid Servs., *Nearly All Eligible Hospitals Are Reporting Quality of Care Data* (2004), http://www.cms.hhs.gov/media/press/release.asp?counter=1188.

    69. Latham & Watkins LLP, *CMS Issues Guidelines on Reporting Hospital Quality Data to Obtain Payment Update Under Medicare Prescription Drug Act* (2004), http://www.lw.com/resource/Publications/ClientAlerts/clientAlert.asp?pid=936.

    70. *Id.*

VA hospitals had launched their own specific safety measures.[71] The VA has developed several patient safety initiatives including both mandatory and voluntary reporting systems, discrete patient safety improvement projects, and the creation of economic and punitive incentives to improve performance.[72]

B. *Reporting JCAHO and the States*

In addition to agency activities, there has been an ongoing debate over the enactment of a federal patient safety bill. In July of 2005, the U.S. Congress enacted the Patient Safety and Quality Improvement Act of 2005 ("P.L. 109-41"), a reasonably detailed response to the problems of medical errors.[73] Under P.L. 109-41, physicians and other providers may voluntarily report confidential and privileged patient safety information, referred to as patient safety work product ("PSWP"), to federally certified regional entities, such as patient safety organizations ("PSO"s), which are run as either public or private entities.[74] The PSOs will analyze the reported data and report out only nonidentifiable PSWP data, which, in turn, may be linked to a network of national databases run by the Department of Health and Human Services ("DHHS").[75] The identifiable patient and provider data reported to PSOs cannot be used in civil, criminal, or administrative proceedings, nor disclosed under the federal Freedom of Information Act. However, source data, such as patient information found in hospital records, will still be subject to the dictates of applicable state discovery and collection laws.[76]

While this new law is an interesting step, reached after several years of deadlock, it raises issues about whether hospitals will develop reporting practices for quality data that will attempt to shield this information from discovery. From a logistical standpoint, current institutional practices in quality data collection will need to be reevaluated, and separate collection practices may need to be developed for federal reporting purposes. From a bureaucratic standpoint, it remains to be seen how the new patient safety bureaucracy will be integrated with other, more established DHHS and other federal program efforts in health care quality and error prevention.

Moving outside the ambit of federal activities concerning medical errors, there have been significant regulatory responses at the state level, as well as in the area of private sector regulation. Although reactions to the epidemic in medical

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71. *See* William B. Weeks & James P. Bagian, *Developing a Culture of Safety in the Veterans Health Administration*, 6 EFFECTIVE CLINICAL PRAC. 270 (2000), *available at* http://www.acponline.org/journals/ecp/novdec00/weeks.pdf.

72. *Id.* at 272-74.

73. Patient Safety and Quality Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005).

74. 119 Stat. at 424; 42 U.S.C. 299b-24 (West 2005).

75. 119 Stat. at 424; 42 U.S.C. 299b-23 (West 2005).

76. 119 Stat. at 424*;* 42 U.S.C. 299b-22 (West 2005).

errors have been varied, a consistent response from both public and private regulators has been the creation of reporting programs.[77] To date, as noted, federal legislation has only proposed a national reporting system, however, a growing number of states and JCAHO have actually developed medical error reporting programs which are designed not only to identify safety problems, but also to foster analyses of problem areas and spark prevention strategies.[78] Error reporting is not a novel concept in the hospital world as state error reporting laws in several jurisdictions have been in place for awhile. Though more commonly internal to the hospital, reporting and analyses of serious incidents is a well-established practice in the context of risk management.[79]

With the development in 1995 of its sentinel event program, JCAHO has taken the lead in error reporting. JCAHO defines a sentinel event as an "event [that] has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition."[80] The occurrence of a sentinel event triggers what JCAHO refers to as a root cause analysis: a systematic investigation directed toward identifying the most basic, or causal, factor or factors that underlie a variance in performance.[81] A major part of the root cause analysis entails the institution's development of policies and procedures that mitigate against the reoccurrence of the event in question. Under the sentinel event policy, JCAHO encourages hospitals to report to the accreditor sentinel events, root cause analysis processes, and findings concerning adverse events which resulted in death or serious injury.[82] JCAHO sees the reporting system as an educational tool in that lessons learned from serious incidents and responses can be shared with other health care institutions. While the sentinel event program has been altered several times since its inception in 1996, the process promoted by the private accrediting agency has been very visible and reactions to it have framed the current debates over key aspects of public medical error reporting initiatives.

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77. *See* Chiang, *supra* note 27. There are a wide range of reporting requirements found in state laws affecting hospitals. *See e.g.*, CAL. BUS. & PROF. CODE § 2226 (West 2005), WASH REV. CODE § 70.41.200 (2005), 18 VT. STAT. ANN. § 9405b (West 2005), which reference hospital reporting mandates in California, Washington, and Vermont, respectively. In addition, hospital risk management entails internal reporting, mandated in state law. *See* R.I. GEN. LAWS § 23-17-24 (2005), MD. CODE ANN. HEALTH-GEN. § 19-319 (West 2005), FLA. STAT. § 395.0197(1) (West 2005).

78. *See* CAL. BUS. & PROF. CODE § 2226 (West 2005); WASH. REV. CODE § 70.41.200 (West 2005); 18 VT. STAT. ANN. tit., § 9405b (West 2005); R.I. GEN LAWS § 23-17-24 (West 2005); MD. CODE ANN. HEALTH-GEN. § 19-319 (West 2005); FLA. STAT. § 395.0197(11) (West 2005).

79. A. Michelle Kuhn, *The Importance of Early Identification in the Claims Management Process*, *in* ESSENTIALS OF HOSPITAL RISK MANAGEMENT 43, 189-194 (Barbara J. Youngberg ed., 1990).

80. JCAHO, Sentinel Event Policy and Procedures, http://www.jcaho.org/accredited+ organizations/sentinel+event/se_pp.htm (last visited June 15, 2005).

81. *Id.*

82. *Id.*

One frequent point of debate is the question of whether or not medical error reporting should be mandatory or voluntary. Critics of JCAHO have pointed to the low number of sentinel events that have been reported in contrast to the increasingly larger projections about the number of medical errors, and these critics have concluded that only a mandatory reporting of all serious incidents can result in a helpful database on errors, and to a lesser extent act as a deterrent against future errors.[83] Those who are proponents of voluntary reporting argue that mandatory reporting takes on a punitive cast and that rather than spark openness and dialogue, obligatory reporting results in institutions hiding problems.[84] Clearly, the JCAHO position won favor in Congress in the new Patient Safety and Quality Improvement Act of 2005, and undoubtedly Federal politics were such that support for mandatory reporting may not be feasible.[85]

Another core issue raised by the JCAHO sentinel event program concerns the nature of what should be reported. JCAHO requires only reporting of episodes which resulted in death or serious injury, but critics point out that the reportable universe is too narrow.[86] Drawing on the experiences of aviation accident reporting, it has been argued that so-called near misses should also be reported in that emerging problem areas could be addressed prior to their actualization.[87] There has also been considerable controversy surrounding the ability of JCAHO to protect reported medical errors and root case analyses from legal discovery.[88] The discoverability question raises a number of issues about the applicability and scope of state peer review protections and has resulted in JCAHO developing a four fold approach to reviewing error data, geared to the idiosyncrasies of law in a given jurisdiction.[89]

The Institute of Medicine also has been a strong proponent of medical error reporting, but, unlike JCAHO, the IOM has called for a system of mandatory reporting by hospitals and other health care institutions of adverse events that lead to death or serious bodily harm, and in the case of near misses, the IOM recommends that voluntary reporting occur.[90] Additionally, the IOM argues that reported information on errors should be protected from discovery when the

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83. *See* Furrow, *supra* note 27, at 207-09.

84. Liang, *supra* note 27, at 346.

85. Todd Sloane, *Not Much of a Cure; a Healthcare Quality Act That's Worse than No Law at All*, MODERN HEALTHCARE, Aug. 8, 2005, at 21; *see also* Terry Hyland, *Medical Errors: New Law Called Good First Step, But Questions Remain on Details*, 14 BNA HEALTH LAW REPORTER 1041 (2005).

86. Furrow, *supra* note 27, at 203-06. *See also* Nancy LeGros & Jason D. Pinkall, *The New JCAHO Patient Safety Standards and the Disclosure of Unanticipated Outcomes*, 35 J. HEALTH L. 189, 192 (2002).

87. *See* Paul Barach, *The End of the Beginning: Lessons Learned from the Patient Safety Movement*, 24 J. LEGAL MED. 7, 20-24 (2003).

88. *But see* IOM, PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE 257-58 (Philip Aspden et al. eds., 2004).

89. JCAHO, *supra* note 80.

90. Barach, *supra* note 87.

reported information is used by peer review entities.[91] The position of the IOM on reporting has been influential at the state level in that a growing number of states have enacted laws that make reporting of certain medical errors to a governmental authority mandatory, and, in turn, these state laws safeguard the confidentiality of reported information, protecting this data from discovery or use in legal proceedings.[92]

By the end of 2002, twenty states had enacted legislation requiring the reporting of adverse events at hospitals as part of their state licensing requirements.[93] States have also faced the challenge of deciphering the types of events that should be reported.[94] At the urging of the IOM, states have relied on the NQF Serious Reportable Events in Healthcare list as the basis for determining what incidents should be reported. The NQF list of twenty-seven egregious adverse medical events is seen by most states as a starting point, and many state mandatory reporting systems are broader in nature, requiring the reporting of events that present strong indicators of quality of care, as well as "near misses."[95] Minnesota is the first state to have adopted use of the entire list of twenty-seven NQF adverse events measures for reporting purposes, characterizing these incidents as "never events," ones that should never occur under any circumstances.[96]

Within fifteen days of the discovery of an adverse event covered in the mandatory reporting list, Minnesota hospitals are required to report the event to the Minnesota Department of Health ("MDH") and to conduct a root cause analysis.[97] The MDH is mandated to publish a report on adverse hospital events annually, together with recommendations for changes, and reported information is to be made available to consumers.[98] Specified adverse events are to be reported by Minnesota hospitals via the web and these data are required to be protected from discovery. In its first two years of operation the Minnesota program is being totally funded by the private sector, but will eventually become a state fiscal responsibility.[99]

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91. *Id.* at 25.

92. *See* state laws mentioned in *supra* note 77.

93. Jill Rosenthal & Maureen Booth, *Defining Reportable Adverse Events: A Guide for States Tracking Medical Errors* (2003), *available at* http://www.premierinc.com/washington/trustees/docs/nashp-reporting-adverse-events.pdf.

94. *Id.*

95. *The National Quality Forum is Setting Standards for Primary Care*, AM NEWS, Jan. 12, 2004.

96. Nat'l Ass'n of Health Data Orgs., *MN Mandates Reporting of Medical Errors Using NQF Measures* (2003), http://www.nahdo.org/projects.asp?page=news&currentpg=12&option=display&id=202.

97. Minnesota Hospital Association, *Minnesota Implements New Reporting System for Adverse Health Events in Hospitals*, 2-3 (2004), http://www.mnhospitals.org/inc/data/pdfs/AHE_Background.pdf.

98. Nat'l Assn of Health Data Orgs., *supra* note 96.

99. Minn. Hosp. Ass'n, *supra* note 97, at 2, 5.

Perhaps the most comprehensive medical error initiative at the state level is occurring in Pennsylvania.[100] As part of a broad package of medical malpractice reforms, Pennsylvania enacted Act 13 in 2003 that created the Patient Safety Authority, a public entity charged with oversight of the medical error issue, addressing the matter as a systemic problem, as opposed to a matter of individual fault.[101] The Pennsylvania law requires that hospitals, birthing centers, and ambulatory surgery centers report serious events that cause death or compromise patient safety, resulting in an unanticipated injury, to both the newly created Patient Safety Authority and the state Department of Health.[102] Incidents and events that could have injured a patient, but did not, and also did not require additional medical services, must be reported only to the Patient Safety Authority.[103]

A key element in the Pennsylvania medical error legislation is the requirement that reporting entities must give patients written notice of serious event occurrences within seven days of their discovery.[104] The law requires the development of an internal safety bureaucracy within covered entities, entailing the appointment of a patient safety officer, the creation of a working patient safety committee, and the drafting of an institutional safety plan to be approved by the state Department of Health.[105] The materials developed within the institution prepared in compliance with the statute are confidential, and not subject to discovery or admission in a civil or administrative action.[106]

The Pennsylvania law is funded through a surcharge imposed on licensed beds in the covered facilities. Implementation of the new law has proven complex as the reported errors are to be gathered and analyzed by an outside vendor that must be determined through a government contracting process. More significantly, the new law must be coordinated with a 1997 provision under the state Health Care Facilities Act which mandates reporting of a more limited range of errors and further coordination must occur with the Pennsylvania Department of State that regulates physicians.[107] The implementation of the Pennsylvania law is still ongoing, and will be closely watched by other states, as

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100. Medical Care Availability and Reduction of Error (MCARE) Act, 40 PA. CONS. STAT. ANN. § 1303.101 (West 2004).

101. 40 CONS. STAT. ANN. § 1303.303 (West 2005) *amended by* 2005 Pa. Legis. Serv. (West), 40 CONS. STAT. ANN. § 1303.304 (West 2002).

102. 40 PA. CONS. STAT. ANN. § 1303.313(a) (West 2004).

103. § 1303.313(b).

104. 40 PA. CONS. STAT. ANN. § 1303.308(b) (West 2002).

105. 40 PA. CONS. STAT. ANN. § 1303.307 (West 2002).

106. 40 PA. CONS. STAT. ANN. § 1303.311 (West 2002).

107. Jane-Ellen Robinet, *Slow Start for Patient Safety Authority*, PHYSICIAN'S NEWS DIGEST, Apr. 2003, *available at* http://www.physiciansnews.com/cover/403.html.

well as by parties within the Commonwealth who are expecting the law to produce measurable results.[108]

IV. STEPPING BACK CATEGORIES AND ANALYSES

A. Models

The regulatory responses to the medical error crisis represent approaches that to an extent fall into five of the seven models of regulation previously discussed, namely, command and control, inspection, reporting and disclosure, delegated regulation, and performance-based regulation. The respective categories overlap in that various types of regulation are vetted through the administrative law process, and as such, it seems safe to conclude that much of the governmental response falls into the command and control approach, which is the dominant regulatory model followed in the hospital sector.[109] Still, within that broad ambit of command and control regulation, distinct approaches to controlling medical errors are noticeable, in particular, reporting and disclosure. In fact, it could be argued that at this early stage in dealing with medical errors, the mandate to report information on errors is the dominant regulatory response. But as medical error issues have sparked changes in licensure laws, the various related inspection processes will be impacted as well.

In addition, delegated regulation is in evidence as the JCAHO sentinel event reporting process impacted accredited facilities and shaped public policy in the area, acting as a catalyst for government action. Particularly noteworthy is the use of performance-based regulation within the federal quality arena as a new mechanism to link payment with behavior. Also of interest is the fact that the health insurance sector is beginning to consider withholding payment for care when a medical error has occurred.[110] Even the two regulatory models, public utility regulation and market regulation, may eventually be avenues for controlling medical errors. It is conceivable that medical error and patient safety could become elements considered in state certificate-of-need programs, and over time changes in hospital behavior may have market implications as safety records become significant issues in consumer choice.

B. Regulatory Responses: Are They Working?

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108. Jane-Ellen Robinet, *supra* note 107.

109. AHA TASKFORCE, *supra* note 10, at 3-4.

110. Tracey Walker, *Minimizing Medical Errors is on Healthcare's Docket*, MANAGED HEALTHCARE EXECUTIVE, Dec. 1, 2004, at 1, *available at* http://www.managedhealthcareexecutive.com/mhe/article/articleDetail.jsp?id=136678.

At this juncture it is premature to assess whether the regulatory responses to medical error issues and commensurate attempts to enhance patient safety are succeeding. The nature and dimensions of the medical error crisis are still unfolding, and so too, will the regulatory responses. Still a certain degree of skepticism about the effects of current medical error regulation seems in order, based generally upon what can be seen as shortcomings in hospital quality regulation. If the concept of quality is thought of in very broad terms, it can be argued that much of the regulation which impacts hospitals, previously reviewed in a very general way, has a nexus to quality, whether it be structure-, process- or outcomes-related. Not only have there been ongoing regulatory efforts to effect quality of care, ranging from licensure to mandated peer review, but the common law - through medical malpractice and institutional responses to liability, such as risk management - can also be seen as a legal process that should have enhanced quality. It is not unreasonable to conclude that the crisis in medical errors has occurred in part because of a failure in regulation, as hospital-based errors are occurring within this highly regulated environment.

On the other hand, some may argue that were it not for regulation, the number of errors may actually be even greater, but arguments either pro or con concerning the broad impacts of regulation on hospital quality, and more specifically on medical errors, are ultimately all matters of speculation. The fact is that it is impossible to gauge the effectiveness of quality regulation in a conclusive fashion, but certainly questions about the effectiveness of past and present regulatory strategies in the quality arena give credence to arguments for exploring regulatory alternatives in this area.

Questions of the viability of hospital quality regulations mesh with broader concerns over the excessive number of acute care regulations, the increasing tendency to develop issue-related regulations, the lack of harmonization of state and federal requirements, and the capacity of the field to absorb, respond to, and finance new mandates.[111] The medical error issue is an ideal area for exploration of new regulatory formats in that it covers an array of problems that manifest themselves at varying levels from hospital to hospital, and the issue is characterized by considerable uncertainties about the most appropriate manners of response. The fact that the key regulatory initiative in the area is reporting and disclosure demonstrates that there is still a great deal to learn about the nature and scope of the medical error problem.

An even larger question about reporting is whether such mandates will actually result in changes in processes and culture that are necessary if patient safety is to be enhanced. Part of the current regulatory difficulty at the federal level in responding to medical errors stems from the fact that new patient safety measures are incorporated within this area within the traditional context of established quality assurance programs. Unquestionably, the medical error issue is a type of quality problem, but patient safety measures, such as assuring that a

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111. AHA TASKFORCE, *supra* note 10.

wrong limb is not amputated or the correct medication is given, are hardly sophisticated matters comparable to those which characterize AHRQ clinical research activities. Patient safety may be more compatible with industrial engineering, human resource management, and staff education than with complex clinical quality considerations. It is certainly reasonable to argue that patient safety does not necessarily equate with optimal quality of care, as the fact that a patient was not injured does not necessarily mean that the care provided was appropriate. Unquestionably, preventing medical errors and ensuring patient safety are clearly linked to quality, but they are areas that lie at the baseline of quality and may be better addressed outside the framework of traditional clinical improvement processes.

V. New Governance – New Models

The recognition that regulation in the hospital sector may not be optimal, and that pursuing solutions to the medical error crisis through current regulatory pathways could falter, only leads to the greater challenge of determining what type of regulatory strategies might be more appropriate to enhance patient safety. In the broader area of regulation generally, there has been a growing movement in legal theory to develop alternative regulatory models.[112] The search for alternative avenues of regulation is sparked by a desire to interject more flexibility into the regulatory process, allow greater input into regulations from the micro-level, and devise regulatory schemes that are capable of targeting regulatory requirements to the level of problems encountered in a given entity. In a broad sense, the goal of legal theorists positing new models of regulation is to formulate a strategy for regulation that lies between the poles of the traditional command and control regulatory format characterized by administrative rule making, and the relinquishment of regulation to free market controls. A number of novel and distinct regulatory strategies are emerging in search of a viable middle ground, and many of these alternatives share commonalities of being more participatory, open-ended, flexible, and adaptive to change.[113]

From a theoretical standpoint, new middle ground regulatory approaches fall into the generic classification of new governance.[114]   A widely studied, and somewhat older alternative model in the area of new governance, is responsive regulation in which a regulated party negotiates enforceable conditions of regulation with the regulator, a hierarchy of sanctions are developed to match degrees of infringements, and a role for the public in regulatory decision-making

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112. Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 343 (2004).

113. *Id.*

114. *Id.* at 344. *See also* Bradley C. Karkkainen, *"New Governance" in Legal Thought and in the World: Some Splitting as Antidote to Overzealous Lumping*, 89 MINN. L. REV. 471, 473-75 (2004).

and monitoring is created.[115] In the context of medical errors, one emerging regulatory model, known as management-based regulation, appears to provide a fruitful alternative, and seems somewhat compatible with current regulatory directions being followed by CMS.[116]

A. Management-Based Regulation

Management-based regulation is a mechanism that directs regulated entities to engage in planning processes that are self determined to meet a particular public goal, such as enhancement of patient safety.[117] Commentators Coglianese and Lazer, who have written extensively on management-based regulation, distinguish this form of regulation from rules that mandate certain technologies or behaviors, so-called technology-based regulation, as well as from regulations which require certain outcomes be performed or avoided, so-called performance-based regulation.[118] Unlike technology-based regulation, which intervenes at the action stage of organizational behavior, and performance-based regulation that concerns outputs, management-based regulation is focused on planning.[119] The rationale underlying regulatory intervention at the planning stage is that sound planning will spark good internal management, resulting in achievement of public goals. The planning process is heavily dependent on information, and the nature and type of information used in planning may be largely a matter of self-determination on the part of the regulated. Uses of information in management-based regulation for planning purposes are distinguished from the information mandates of collection and disclosure that are so prevalent in medical error regulation, and would better be classified as technology or process regulation.

Unlike other forms of new governance, management-based regulation is not just a theoretical construct, but has actually been used in a number of areas such as safety regulation in the food and occupational arenas, as well as in pollution prevention, all enterprises that are characterized by extensive technical considerations.[120] In the food safety field, the USDA and the FDA have adopted a globally accepted regulatory strategy, Hazard Analysis and Critical Control Point ("HACCP"), that requires food producers to identify hazards, assess risks of hazards, identify the best methods for dealing with hazards, and make necessary changes to avoid future problems.[121] Non-binding guidelines on how

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115. IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1995).

116. Conditions of Participation for Hospitals, 68 Fed. Reg. at 3435.

117. Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 L. & SOC'Y REV. 691, 694 (2003).

118. *Id.* at 701-02.

119. *See id.* at 694.

120. *Id.* at 702.

121. FDA Backgrounder, *HACCP: A State-of-the-Art Approach to Food Safety* (2001),

to create an HACCP plan have been developed by regulators and plan compliance is monitored, but food producers have considerable leeway in devising their plans and managing risks.[122]

As the brief example of food safety indicates, management-based regulation is more flexible than a command and control approach, but it is not totally open-ended. The management-based regulatory model can be developed in a number of ways depending upon the goals of regulators and the likelihood of industry compliance. Clearly a major issue for any regulator in pursuing a regulatory strategy is cost. It may seem that self-generated approaches to problems through management-based regulation may be cheaper than mandated ones, but such a conclusion may not be warranted as considerable internal efforts need to be made in a management-based regulation scheme that could be quite costly.[123] In addition, if management-based regulation is added onto current regulatory structures, such an addition may actually increase costs.

There is also a determination that needs to be made as to whether all the actors in a given field have adequate capabilities to devise and implement an effective, internally generated plan. Within the context of management-based regulation, questions need to be addressed about how directive government authorities should be.[124] For example, should regulators merely require that the regulated entity engage in planning in a given area, without providing directions about the elements of the required plan, or should planning be a more prescribed process, with planning elements specified by the regulator, and plan approvals required? Beyond the plan itself, there needs to be consideration about how much monitoring government should engage in over plan implementation, and whether record keeping, inspections and third-party audits will be required.[125]

Management-based regulation appears to be most viable in areas that are highly technical and where solutions to problems may be unique to individual circumstances. It would seem that management-based regulation fits well into the patient safety area, in that insuring safety and preventing medical errors represents a wide range of complex clinical and operational matters, and problems encountered from hospital to hospital may vary significantly. The fact that public and private entities are concentrating safety prevention on a number of discrete priority areas does not negate the fact that the area is broad, multifaceted, and variable.

1. The CMS QAPI as a Model

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http://www.cfsan.fda.gov/~lrd/bghaccp.html.

122. FDA Backgrounder*, supra* note 121.

123. Conditions of Participation for Hospitals, 68 Fed. Reg. at 3435 (*see* Designing Management-Based Regulation).

124. Coglianese & Lazer, *supra* note 117.

125. *Id.* at 718-19.

If management-based regulation is to be considered in the medical errors context, a sound jumping off point would be the CMS QAPI program previously discussed.[126] In fact the QAPI program, as it is currently constituted, can be characterized as a type of management-based regulation. The regulatory structure of QAPI is a planning model that allows for considerable discretion on the part of the hospital to design a quality assessment and performance program that demonstrates improvements in healthcare outcomes and reduction of errors. The regulation is designed to allow hospitals the flexibility to structure programs that are tailored to their individual situations. The regulations do not require prior approval of hospital QAPI programs, but the process is not open-ended as there is considerable specificity provided in the regulations about the overall framework of these programs.[127] Hospital programs must be institution-wide, be measurable (in reference to both clinical outcomes and error reduction), use specified data elements, include ongoing corrective action measures, and include the development of specific projects to reduce errors in discrete areas. The QAPI regulations place responsibility for program operations on hospital leadership (board, medical staff), and individual institution programs must be evaluated as part of the CMS institutional survey process to determine compliance; failure in the area could lead to termination from the Medicare and Medicaid programs.[128]

While QAPI represents a major departure from the command and control model traditionally followed by CMS, it is clearly a model of management-based regulation which reflects considerable government involvement at the planning and implementation phase. CMS is now working toward the development of standardized performance and data collection that would become part of the QAPI program, further underscoring the fact that the regulator will continue to be actively engaged in shaping the framework of this program.[129] It may be unreasonable to expect that CMS would delegate the reduction of medical errors to the hospital community without considerable oversight on their part, not only due to concern over the impacts of change in regulatory policy, but also because there is considerable expectation that the agency will deal effectively with this major policy challenge. The movement toward regulatory flexibility represented by QAPI must also be viewed cautiously for if real results do not occur within the context of the program, it is not unreasonable to expect that the agency will revert back to the command and control approach.

2. ISO 9000: An Emerging Alternative

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126. IOM, *supra* note 7.

127. *Id.*

128. *Id.*; Conditions for Participation for Hospitals, 68 Fed. Reg. at 3435, 3443, 3446.

129. Conditions of Participation for Hospitals, 68 Fed. Reg. at 3444.

At the risk of pushing an idea too far, it seems appropriate to consider whether any other management-based regulatory models might be found to deal with medical error issues beyond QAPI. The desire to identify another management-based regulatory model to enhance patient safety is prompted not only by a desire to expand the range of possible applications of this regulatory approach, but by the limitations of the QAPI program. Experts on medical error have reached consensus that prevention of errors will require not just a response to individual problems but rather the development of systems and processes that are responsive to patient safety, and are inclusive of all operational aspects of an institution.[130] QAPI may ultimately lead to the creation of error prevention systems within hospitals, but the regulation as it is now constituted is very oriented toward identifying and correcting particular, self-selected problem areas. Within the context of management-based regulation, a more systems-oriented model can be found in an established quality management system, the ISO 9000 series standards.[131] The International Organization for Standardization that created the ISO 9000 series is an internationally recognized entity that has overseen the development of quality standards that touch on all activities in an organization that determine quality policies, objectives and responsibilities, related planning, controls, and specific approaches to quality assurance.[132] The main purpose of these standards is to establish a consistent and high level of quality practices that require organizations to implement quality systems—formal organizational policies, processes, and procedures that meet the needs of the entity's customers (patients).[133] ISO 9000 is, in fact, a common reference for a group of generic quality standards (ISO 9000 through ISO 9004) that are both advisory and procedural in nature.[134] When an organization demonstrates compliance with ISO standards to a third-party review entity (the registrar), the organization's quality system, not the entire entity, is registered as being compliant.[135] The standards, designed originally for manufacturing, have been applied recently to service sectors, including health care.

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130. Rene Amalberti et al., *Five System Barriers to Achieving Ultrasafe Health Care*, 142 ANNALS OF INTERNAL MED. 756 (2005).

131. Michael G. Crago, *Patient Safety, Six Sigma & ISO 9000 Quality Management*, QUALITY DIGEST, Nov. 2000, *available at* http://www.qualitydigest.com/nov00/html/patient.html; Laura D. Prioli, *ISO 9000 Certification for Health Care Organizations*, http://www.ics.sgsna.com/services/Healthcare.htm (last visited July 7, 2005); Barry K. Hall & Stephen H. Trexler, *ISO 9000 White Paper "Increasing Profitability, Quality and Compliance with ISO 9000"*, http://www.rosternetwork.com/bna/iso_9000_white_paper.htm (last visited Nov. 5, 2005).

132. *See* Crago, *supra* note 131.

133. Medical Device Safety Reports, *ISO 9000 Series Standards: What Healthcare Facilities Need to Know*, http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8278 (last visited Nov. 5, 2005).

134. Myra Ellen Edelstein, *How ISO 9000 Standard Could Improve Quality*, MANAGED CARE MAGAZINE, Nov. 1998, *available at*
http://www.managedcaremag.com/archives/9811/9811/iso.html#how.

135. Medical Device Safety Reports, *supra* note 133.

The concept of quality manifest in ISO 9000 focuses on four broad areas: generating outputs that meet customer (patient) specifications, creating quality systems which are consistently implemented and verifiable, ongoing monitoring of quality systems, and efforts directed toward continuous quality improvement.[136] Within the ISO 9000 series, the ISO 9001:2000 standard relates most directly to health care quality. The 9001:2000 quality standard rests on eight well-accepted quality management principles: customer focus, leadership, involvement of all personnel, process approach, systems approach to management, continual improvement, factual approach to decision making, and positive supplier relationships.[137] The ISO 9000 process requires that all systems and procedures be documented for every organizational activity that has a direct or indirect impact on quality in areas affecting costs, unit performance, and customer satisfaction. For purposes of this system, hospital activities can be broken down into clinical services, functional departments, and administration, and in each of these areas, ISO 9000 standards require creation of quality measures which cover both internal process and outcome matters, as well as external considerations such as regulatory compliance.[138] Within each of a hospital's documented operational areas touching on patients, safety measures would clearly be incorporated as essential elements of quality, not only as a matter of enhancing clinical excellence, but more basically, as a mandate to protect patients from any type of harm. ISO 9000 processes involve clinical and support staff and administration in planning and implementation. Success in making quality systems work within a given hospital requires knowledge on the part of all personnel of developed policies and procedures, particularly in areas such as patient safety.

The ISO 9000 standards are widely used by hospitals around the world, but are only now being considered in the United States. In part, consideration of adopting ISO 9000 can be seen as a reaction against what is perceived as an overly prescriptive JCAHO accreditation process, but it is also seen as a mechanism of private regulation that allows an entity to structure its own approaches to quality and safety, integrating various quality related processes into a single framework.[139] While ISO allows for autonomy in program design and

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136. *See* Lucid International, *Basic ISO 9000 Information*, http://www.iso9000commerce.com/iso_intro.htm (last visited July 7, 2005). *See also* Hall & Trexlor, *supra* note 131.

137. *See generally*, BRYCE E. CARSON, ISO 9001-2000, A NEW PARADIGM FOR HEALTHCARE (2004); *see also* Praxiom, ISO 9001 2000 Translated Into Plain English, http://www.praxiom.com/iso-9001.htm (last visited Sept. 16, 2005).

138. Medical Device Safety Reports, *supra* note 133.

139. Frank Diamond, *Proponents Say ISO 9000 Standards are a Less Prescriptive, Ponderous and Costly Way to Review Hospitals. But Are They Truly Applicable to Health Care? The Mountain Named JCAHO Meets the Tremor Called ISO*, MANAGED CARE, Nov. 1998, *available at* http://www.managedcaremag.com/archives/9811/9811.iso.html; *see* Hall & Trexler *supra* note 131.

implementation, an organization must meet broad requirements applicable to its industry. For example, in the hospital area, an institution's failure to practice appropriate sterilization techniques or infection control would constitute nonconformance with ISO standards.[140] To meet program requirements, a hospital must consider what the ISO standards require and correlate the elements of that standard with the particular service in question. In assessing given approaches to quality, the ISO process requires analyses of how adopted hospital processes enhance overall quality, meet patient needs, and reflect state-of-the-art practices.[141] Entities that use the ISO 9000 process can reference health care industry guidelines that deal with quality improvement and planning, specifically the ISO 9001:2000 standard previously noted. An entity can have its compliance with ISO 9000 certified by a registration process conducted by one of fifty-two recognized certification organizations every three years, with ongoing surveillance of parts of the organization's quality system as frequently as every six months.[142]

Beyond theoretical constructs, ISO 9000 is perhaps the most open-ended, applied form of management-based regulation that currently can be referenced in the hospital context. It clearly possesses significant flexibility in that it is structured through a process that is self-determined by a hospital, and the guidance in creating and implementing the process is largely advisory. As noted, however, ISO 9000 compliance is evaluated externally, and there are generic standards that can be referenced as guide points for implementation and assessment. The advantage of using ISO 9000 beyond flexibility and institutional self-direction appears to lie in the fact that this quality process is system-oriented and offers an opportunity to more easily link patient safety to all areas of the hospital, beyond just clinical considerations. Proponents of the current licensure/accreditation system for hospitals argue that ISO 9000 can only be applied to those parts of a hospital that function in a quasi-industrial, process-type mode, and that the standards in this evaluation system are too general, lacking the comprehensiveness and specificity to improve quality found in the JCAHO standards.[143] Interestingly enough, however, ISO 9000 has been promoted in a proposed piece of Pennsylvania legislation as a type of hospital risk management program the application of which is tied to reduced medical malpractice premiums.[144]

3. Reflections on Management-Based Regulation

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140. Medical Device Safety Reports, *supra* note 133.

141. For a basic discussion of the ISO certification process, *see* Simply Quality, Frequently Asked Questions About ISO 9000, http://www.isoeasy.org/faq10.htm (last visited June 12, 2005).

142. Medical Device Safety Reports, *supra* note 133.

143. *See* H.B. 845, 2003 Gen. Assem., Reg. Sess. (Pa. 2003).

144. *See* H.R. 162, 183d Gen. Assem., Reg. Sess. (Pa. 1999) (resolution commending a Pennsylvania school district on its achievement of ISO 9000 certification).

Some form of management-based regulation may offer regulators an attractive alternative to existing regulatory models in the hospital area generally. In the case of medical errors, management-based regulation provides a flexibility that could lead to more creative approaches to both identifying and correcting problems. Management-based regulation seems particularly attractive in the patient safety area in that this regulatory model is well suited to an area characterized by technicalities, uncertainties as to cause and response, and disparities across the field in both the type and extent of problems. At most, management-based regulation may be a long term vehicle to spark a regulatory make-over of the hospital field, and at the least, it would be an experiment in regulation that could more effectively engage the regulated in a way that is not merely focused on compliance.

Undoubtedly, the movement to management-based regulation would be a major change in the manner in which regulators deal with hospitals, and while the CMS QAPI program signifies a willingness on the part of a regulator to adopt a more flexible regulatory scheme, that program must be viewed cautiously as it is both new and possibly transitional. The broader history of hospital regulation depicts a story of considerable rigidity in approaches to controlling hospitals, so it seems reasonable to conclude that adoption of new models will be challenging and gradual. There is also a reality that must be confronted that merely using a new model will not, in and of itself, be effective unless certain surrounding factors are taken into account in the application of that model.

For management-based regulation to be effective, at least four factors must be considered. First, while this model offers considerable flexibility on the part of the regulated, there still needs to be certain policy guidance provided by the regulator. In the medical error context, objectives need to be spelled out beyond error prevention and enhancement of patient safety. While regulators may not need to detail a list of medical errors that must be addressed, some direction about the overall structure of a program of error prevention is necessary to ensure that regulatory compliance is meaningful. Secondly, there needs to be a major change in the role of the regulator. Rather than focusing on enforcement and compliance, regulators will need to become more collaborative and consultative in their posture to the regulated. In a sense, changing the regulatory role to one of acting as a consultant to the field will require more hands-on involvement in facility operations and a greater knowledge of the patient safety area than is required in an enforcement role. The flexibility present in management-based regulation will afford regulators the ability to recommend a range of responses that would not be possible in a traditional regulatory scheme. Thirdly, hospitals must be willing to support a new approach to regulation that will engage the institution in a problem-solving mode, which is much different from a posture reactive to regulations that stresses doing only what is required to comply with a mandate. It will only be through considerable internal efforts that management-based regulation will succeed in that processes like ISO 9000

require institution-wide engagement, from planning to implementation. For hospitals to effectively pursue creative patient safety measures, there needs to be a certain level of trust developed on their part toward regulators that alternative approaches to dealing with medical errors will be fairly evaluated and allowed to evolve. Finally, the movement toward management-based regulation in the patient safety area should not be seen as an all-or-nothing proposition. A movement toward a more flexible regulatory model may be accompanied with other traditional approaches to the problem of medical errors, such as identification and reporting. Regulators will need to balance diverse regulatory approaches to insure that new models are allowed to operate along side of traditional regulation and that new approaches are given adequate time to prove their value. They must also be tolerant of compliance efforts that are not uniform.

VI. CONCLUSION

Comparing the current crisis in medical errors to a Jackson Pollack painting appears apt as the picture we are currently seeing is confusing, chaotic, and subject to an array of interpretations. The medical error issue has taken on a longer life than may have been predicted even after the first IOM report, as the scope of this issue continues to evolve and broaden. It is likely that the medical error crisis, and the related attempts to protect patient safety, will prompt a wide array of diverse clinical and operational responses, some uniform in character and others highly anecdotal. The regulatory responses to medical errors are also evolving, but caution must be exercised here as new regulations appear to be framed within the context of traditional models that have been identified as increasingly problematic in the hospital context. While it may be premature to judge particular regulatory efforts in the medical error context, it seems that the primary response of mandated reporting is a very preliminary reaction that undoubtedly will help us to understand the dimensions of the issue. Whether such an understanding will lead to tangible improvements, however, is still an open question. If medical errors are to be reduced and patient safety enhanced, consensus is emerging that hospital-based systems, clinical and operational, must be developed and/or improved. It would appear then, that regulation in the area should be sparked by a dual imperative. On the one hand, the emerging and evolving medical error arena should be viewed as an opportunity for regulators to break new ground and create a regulatory scheme that allows the regulated the opportunity to exercise meaningful input in framing and solving the problem and in turn, place the regulatory agency into more of a collaborative and consultative role. On the other hand, the regulatory solution must be sensitive to the need not only to deal with individual patient safety problems, but also to allow individual hospitals to create a platform for the development of viable system approaches to the issue generally. It appears that the regulatory model of management-based regulation which comes from the broader area of new

governance presents a viable alternative for government to confront medical errors, whether that model is framed along the lines of the CMS QAPI program or the generic ISO 9000 quality model. What is proposed in this piece is undoubtedly a major change in the nature of hospital regulation that will be difficult for regulator and regulatee alike, but regulatory policies must always be subservient to the public good and the formats in which such policies are incorporated are only tools to effectuate safety goals, not ends in and of themselves.