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Barry R. Furrow

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Introduction

Medical care injures and kills patients. The Institute of Medicine came up with the now familiar projection of up to 98,000 deaths per year, and hundreds of thousands of unnecessary injuries and extra days of hospitalization.[1] The Utah-Colorado Medical Practice Study (UCMPS) found that adverse events connected to surgery accounted for about half (44.9%) of adverse events across both states, with only 16.9% of the surgical adverse events involving negligence.[2] The authors concluded that the UCMPS produced results similar to the earlier New York Harvard Study—three to four percent of all hospitalizations give rise to adverse events.[3] These data suggest that iatrogenic injury is a significant, enduring, and innate feature of the United States hospital system.[4] A new survey of patients by the Commonwealth Fund concludes that nearly 22%

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* Director, The Health Law Institute, Widener University School of Law 4601 Concord Pike, Wilmington, Delaware 19803.

[1] Institute of Medicine, To Err is Human: Building a Safer Health System 26 (Linda T. Kohn, et al., eds., 2000) (revealing that medical error is a leading cause of death and injury), available at http://www.nap.edu/books/0309068371/html/ [hereinafter Institute of Medicine].

[2] Eric J. Thomas, et al., Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado, 38 Med. Care 247-49 (March 2000) (reporting results of 15,000 randomly sampled nonpsychiatric discharges in 1992).

[3] David M. Studdert, et al., Beyond Dead Reckoning: Measures of Medical Injury Burden, Malpractice Litigation, and Alternative Compensation Models from Utah and Colorado, 33 Ind. L. Rev. 1643, 1662 (2000).

[4] Id.

of patients have experienced a medical error, with adverse drug events the largest contributor to these errors.[5]

System failures account for the vast majority of medical errors in hospitals.[6] Almost 80% of adverse drug events are traceable to a system malfunction.[7] Institutional staffing errors, for example, are often the culprit in patient injury, and long working hours may also contribute.[8]

Adverse drug events are a major contributor to iatrogenic illness in hospitals and may account for nearly 10% of hospitalizations.[9] Errors in administration of drugs by nurses are often a primary cause.[10] Most of these drug errors are due to problems with information access and dissemination.[11] In spite of the high incidence of medical errors, it has been difficult to move quality of care onto the agenda of most health care institutions.[12] Serious quality problems are widespread throughout American medicine.[13]

The American health care system is complex.[14] The federal government funds nearly half of the national health expenditures through its Medicare and Medicaid programs, VA hospitals, and

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[5] Terance Kinninger & Lee Reeder, *Establishing ROI for Technology to Reduce Medication Errors is Both a Science and an Art*, 57 HEALTHCARE FIN. MGMT. 46 (2003) (arguing that information technology holds the potential to reduce medical errors due to hospital system failures).

[6] Lucien L. Leap, et al., *Systems Analysis of Adverse Drug Events*, 274 J. AM. MED. ASS'N. 35 (1995) (noting that as many as two-thirds of medical errors in the county may be the result of errors in system management).

[7] *Id.* (reporting a system analysis of events from a prospective cohort study).

[8] *See* D.I. Orton & John H. Gruzelier, *Adverse Changes in Mood and Cognitive Performance of House Officers After Night Duty*, 298 BRIT. MED. J. 21 (1989) (reporting a controlled study of twenty doctors to determine the cognitive effects of long hours and reduced sleep).

[9] INSTITUTE OF MEDICINE, *supra* note 1, at 26 (reporting a study of 815 consecutive patients at a university hospital).

[10] VIRGINIA A. SHARPE & ALAN I. FADEN, MEDICAL HARM: HISTORICAL, CONCEPTUAL, AND ETHICAL DIMENSIONS OF IATROGENIC ILLNESS 188 (1998) (arguing that such errors could probably be reduced through improved training).

[11] *Id.* at 188 (stating that computerized ordering systems could help to reduce the incidence of such errors).

[12] Mark R. Chassin, et al., *The Urgent Need to Improve Health Care Quality*, 280 J. AM. MED. ASS'N. 1003 (1998) (stating that present quality improvement efforts are "sporadic at best").

[13] *See generally id.*

[14] Some have even argued that, given the complexities of the modern health care system, high rates of medical error should not be surprising at all. *See* Lucian L. Leape, *Error in Medicine*, 272 J. AM. MED. ASS'N. 1851, 1851 (1994) [hereinafter *Error in Medicine*].

CHAMPUS.[15] State governments regulate the delivery of health care within their boundaries.[16] And private insurers impose their own rules on providers who choose to contract with them to offer services.[17] One of the difficult issues to emerge from the Institute of Medicine report, *To Err Is Human*, is how to achieve provider disclosure of medical errors and adverse events, as well as near misses and adverse patient events.[18] Some have proposed the development of a national system through which providers could voluntarily report medical errors and adverse events, but the feasibility of such a system would be limited by providers' fears that the system would attract plaintiff attorneys as surely as honey attracts bears.[19] Reporting of adverse events and near misses is an essential part of an information infrastructure; yet efforts to obtain good data on performance continues to founder on the shoals of system and provider resistance.[20] We have not yet federalized medical error reporting, or quality management generally, although a federal reporting system would move hospitals in this direction.[21] Providers are confronted with varying regulatory forces that relate to medical errors and their discovery.[22] No coordination of reporting is currently mandated in our complex state-federal system, with its market driven insurance component and its powerful civil litigation system

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[15] *See* Centers for Medicare & Medicaid Services, *National Health Expenditures, 2001*, (reporting that the government spent $647 billion in 2001 covering 45% of the nation's health bill), *at* http://cms.hhs.gov/statistics/nhe/historical/highlights.asp (last visited Apr. 19, 2003).

[16] *See generally* Lucian L. Leape, *Reporting of Adverse Events*, 347 NEW ENG. J. MED. 1633, 1634-35 (2002) (noting that only twenty states have mandatory reporting systems for reporting medical errors and few states have experts to analyze more than a small sample of such reports) [hereinafter *Adverse Events*].

[17] *See generally* Jonathan Harding, *Risk Management in an IPA Setting*, 20 PHYSICIAN EXECUTIVE 32 (1994) (explaining how the development of HMOs and other health care delivery systems has given rise to new legal theories of negligence in medical error cases).

[18] *See generally Adverse Events, supra* note 16, at 1636 (describing various approaches to medical error reporting systems and concluding that it is doubtful that a national reporting system would even be feasible).

[19] According to the American Medical Association and the American Hospital Association, increased liability resulting from a mandatory reporting system would deter health care providers from reporting medical errors. *Error in Medicine, supra* note 14 at 1633.

[20] *Id.* (arguing that among physicians, fear of lawsuits, punishment, shame, loss of reputation, and peer disapproval are deterrents to disclosure of medical errors).

[21] *See id.* at 1636 (stating that while some believe a national system would improve the health care system it is doubtful that a national system would be feasible in the United States due to the enormous cost and technical challenges such a system would require).

[22] System wide programs (e.g., the Veterans Affairs program) and specialty-based reporting programs (e.g., those for neonatal and adult intensive care) provide effective oversight, which some commentators have argued should be expanded. *Id.* at 1637.

existing in parallel.[23] In this article I will briefly consider some possible sources of medical error, using recent malpractice cases to illustrate the often-chaotic environment of hospitals. I will then consider various approaches to the problem, in light of the momentum built by the Institute of Medicine report, *To Err is Human*, and earlier work on medical error by Lucian Leape and others, which drew attention to the level of errors within health care institutions. Finally, I will compare the JCAHO and CMS approaches to reporting of medical errors with the new Pennsylvania approach, to better gauge their merits of the approaches.

Pennsylvania has enacted legislation, entitled the Medical Care Availability and Reduction of Error Act (Mcare), that requires mandatory reporting for not only medical errors and serious adverse events, but even requires providers to report "near misses."[24] This Act promises to achieve some of the system self-scrutiny that Institute of Medicine has recommended.[25]

I. ACCOUNTABILITY WITHIN COMPLEX SYSTEMS: WHOM SHOULD WE BLAME?

> [T]here are distinct limitations to the industrial cure, however necessary its emphasis on systems and structures. It would be deadly for us, the individual actors, to give up our belief in human perfectibility. . .It's a necessary part of good medicine, even in superbly "optimized" systems. Operations like that lap chole have taught me how easily error can occur, but they've also showed me something else: effort does matter; diligence and attention to the minutest details can save you.[26]

A movement to restructure health care systems has developed over the past decade, driven by evidence that change is best achieved by a focus on system-wide rather than individual provider error. Total quality management and continuous quality improvement are two examples of borrowing from industry and importation

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[23] *Id.*

[24] *See* 40 P.S. § 1303.308(a) (2002) (requiring provider to report a serious event or incident that the provider reasonably believes has occurred); *See also* 40 P.S. § 1303.302(a) (2002) (defining "incident" as an "event, occurrence or situation involving the clinical care of a patient in a medical facility which *could have* injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient") (emphasis added).

[25] *See* 40 P.S. § 1303.301 (2002) (stating that the Act "relates to the reduction of medical errors for the purpose of ensuring patient safety").

[26] ATUL GAWANDE, COMPLICATIONS: A SURGEON'S NOTES ON AN IMPERFECT SCIENCE 73 (2002).

into the health care setting.[27] My question is one a regulator would ask—how can state or federal law optimize incentives within health care institutions to reduce medical error? The answers are by no means obvious, but a look at some of what we know about systems may provide guidance in shaping future regulatory strategies.

A. Blaming the Individual Provider

The various legal strategies for pinpointing errors and account-ability in health care have historically focused on the individual physician, the primary decision-maker who diagnoses and treats an individual patient.[28] This is understandable given the dominant role that the doctor-patient relationship plays in health care ethics.[29] Until recently, malpractice suits were almost exclusively brought against individual physicians, only reaching institutions through agency law principles or under special circumstances.[30] Moreover, medical discipline is defined by the licensing power of state medical boards over individual physicians, not institutions.[31] Thus, regula-tion has typically started with the individual provider. Physician accountability and blaming pervades our legal assessment of medi-cal errors, and many regulatory initiatives have stumbled on physi-

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[27] *See, e.g.,* Jim Summers & Michael Nowicki, *Managing Organizational Improvement in a Re-source-Challenged Environment,* 57 HEALTHCARE FIN. MGMT. 60 (2002) (describing how healthcare managers have implemented a variety of major organizational-improvement techniques).

[28] *See generally* Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and The Evolution of The American Health Care System,* 108 HARV. L. REV. 381 (1994) (chronicling how courts have gradually developed measures of hospital liability since the 1960s).

[29] *See* Mark A. Hall, *Law, Medicine, and Trust,* 55 STAN. L. REV. 463, 469 (2002) (discussing the psychology of trust in medical relationships).

[30] *See* Abraham & Weiler, *supra* note 28, at 393 (noting that when physicians enter into con-tract with a hospital to deliver emergency care, radiology services, or similar services of-fered by the hospital, then the hospital is likely liable for any malpractice attributable to physicians acting as its agent. "Special circumstances" that may also result in a hospital being held liable for a physician's negligence might exist if a hospital is negligent in grant-ing privileges to a negligent physician).

[31] *See* Ross D. Silverman, *Regulating Medical Practice In The Cyber Age: Issues And Challenges For State Medical Boards,* 26 AM. J.L. & MED. 255, 256-58 (2000) (describing the regulation of the practice of medicine).

cian fears of blame attribution.[32] Physicians agree that our "culture of blame" has had a negative effect on how they practice.[33]

The problem is that medicine has become far more complex than Norman Rockwell imagined. The modern health care system is big business and includes not only physicians, but drug and device manufacturers and their middlemen, pharmacies, testing labs, and thousands of allied health professionals supporting the whole medical enterprise. The courts are beginning to acknowledge the interdependence of providers within health systems, sometimes expanding duties as a result.[34] New regulatory initiatives likewise are shifting the focus to system-wide error detection and prevention, recognizing that the health care system is susceptible to system improvement ideas drawn from other industries.[35]

One of the major issues in medical error reduction is how to induce physicians to change.[36]

Are courts, medical boards, and others who evaluate medical errors signaling that incentives are in place to produce duties that are constructive for providers? My hypothesis is that we do in fact want to "blame" systems—institutions and drug and device manufacturers—since attribution of "blame" is a way of sharpening institutional accountability. In even the most industrialized model of medicine, blaming, when properly done, serves a valuable function

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[32] See Bryan A. Liang, The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in Health-Care and Legal Systems, 29 J.L. MED. & ETHICS 346, 360 (2001) (arguing that, not only does the fear of punishment not reduce mistakes, but it also hinders cooperative approaches to reduce efforts through reporting).

[33] COMMON GOOD, Harris Interactive's Fear of Litigation Study: Executive Summary, at http://ourcommongood.com/news/item?item_id=3244 (reporting that fifty-one percent of physicians believe that, as a result of medical malpractice fears, their ability to care for patients has gotten worse over the past five years).

[34] See Abraham & Weiler, supra note 28, at 393.

[35] See generally, Richard Grol, Improving the Quality of Medical Care: Building Bridges Among Professional Pride, Payer Profit, and Patient Satisfaction, 286 JAMA 2578 (2001) (discussing regulatory and management approaches for improving the quality of the American health care system).

[36] Physicians say they have changed their behavior out of fear of being sued. See, Common Good, Harris Interactive's Fear of Litigation Study: Executive Summary, at http://ourcommongood.com/news/item?item_id=3244. Fifty-one percent said they suggested invasive procedures such as biopsies to confirm diagnoses more often then their professional judgment would dictate; 50% said they noticed other physicians resorting to aggressive treatments of terminally ill patients; 79% said they ordered more tests than they believed were medically necessary; and 74% referred patients to specialists more often than they believed medically necessary. Id. These data indicate that litigation does induce change, but rather unsystematically. Some of this behavior may be positive, however, since many of these practice patterns may do more good than harm.

in searching out, clarifying, and holding responsible the causal agents of harm. Blame connotes moral responsibility, and we want our health care institutions to be held accountable for their errors. Stripping away blame may neutralize responsibility. Errors should matter; blame should follow. The harder question is what to do with such blaming to make it positive. Within the health care institution, blaming individual providers serves little constructive purpose. Error identification requires a comfortable and candid relationship among members of a health care team, built on trust among members that errors may be openly discussed without fear of sanction in all but the most egregious cases. Blaming individuals is often a destructive cross current in our legal approach to error that slows progress.[37]

B. Locating Medical Errors Within Systems: Codman's Vision

Ernest A. Codman, the chairman of the Committee on Hospital Standardization during the early part of the twentieth century, challenged the medical community to take a more scientific approach to the clinical practice of medicine.[38] His system-based approach has been described as,

> [A]n 'end-result system'. . .based . . . 'on the common-sense notion that every hospital should follow *every* patient that it treats, long enough to determine whether or not the treatment has been successful, and then to inquire 'if not, why not?' with a view to preventing similar failures in the future.[39]

Codman's central idea was a complete patient record that included assessments of why a treatment was unsuccessful, including discussion of errors of technical knowledge or risk; lack of surgical judgment; lack of care or equipment; lack of diagnostic skill; unconquerable disease; patient's refusal of treatment; calamities of surgery or accidents and complications over which doctors had no control.[40] This detailed record was to serve an auditing function to evaluate, compare and establish benchmarks for the performance of physicians and hospitals.[41] His idea was revolutionary, aiming to

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[37] *See Error in Medicine, supra* note 14 at 1851 (stating that the culture within the medical community has come to view medical errors as being indicative of negligence, which translates into mistakes being unacceptable and fosters unreal expectations that physicians must be infallible).

[38] SHARPE & FADEN, *supra* note 10, at 29.

[39] *Id.* at 29.

[40] *Id.* at 30.

[41] *Id.* at 31.

assess a hospital's efficiency in therapeutic, outcome-based terms. To Codman, patient harm due to infections or unnecessary or inappropriate surgery was a hospital "waste product."[42]

Unfortunately, the threat to physicians from such performance measurement was clear, and when the American College of Surgeons (ACS) developed their error reporting system, the analysis of patient outcomes and error reporting was omitted—these were Codman's most central ideas for error reduction.[43] His work led eventually to the Joint Commission on Accreditation of Health Care Organizations (JCAHO), which has slowly moved toward a more outcome-based accreditation system.[44]

Iatrogenic harm refers to patient injury caused by a physician.[45] Current systems approaches attempt to draw our attention to the broader framework for errors within the delivery system. A broader definition is needed to capture the reality of modern health care delivery: drugs, devices, hospital infections, nurses, support staff, technicians and all those other factors that support the ultimate doctor-patient treatment.[46] Diffusion of responsibility among members of a health care team often means that instead of no one being responsible for harms from system failures, everyone is – everyone who could have prevented the error.[47] Sharpe and Faden describe this as the ". . .moral imperative behind quality improvement in the delivery of health care,"[48] and propose a shift in terminology from iatrogenic to comiogenic to capture this new focus on systems within institutions:

> On the assumption that errors and communication failures (and the harms associated with them) are largely preventable, quality improvement requires a concerted and systematic effort on the part of administrators and practitioners to identify and anticipate such failures, and to implement processes that make them less likely. It is this broader notion of causal agency and moral accountability that is captured in the shift from the term 'iatrogenic' – which implicates physicians alone–to the term 'comiogenic' – which implicates all health care providers who are directly or indirectly responsible for the care of the patient.[49]

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[42] *Id.*

[43] SHARPE & FADEN, *supra* note 10, at 33.

[44] *Id.*

[45] *Id.* at 117.

[46] *Id.*

[47] *Id.* at 139.

[48] SHARPE & FADEN, *supra* note 10, at 139.

[49] *Id.* at 139.

This shift in terminology does not take us far enough. We also need to place medical error within the larger framework of institutional errors of all kinds. Error in medicine has been viewed as something special, in large part because of the exalted status of medicine in our society and the mystique with which we surround it.[50] If medicine is special, then medical error must also be special. Error in medicine thus tends to be seen as a "special case of medicine rather than a special case of error."[51] Senders writes as follows:

> The unfortunate result has been the isolating of medical errors from much, though not all, of the body of theory, analysis, and application that has been developed to deal with error in other fields such as aviation and nuclear power. Because of the intensely personal nature of medicine and because of the ostensibly curative, helping, and ameliorative nature of the medical process, the consequences of medical error are viewed with more alarm than those in many other enterprises. . . . Much as human behavior in a medical setting is still behavior and not medicine, human error in a medical setting is still error and not medicine. Medical error must be considered to be the result of the expression of error in a situation in which there are medically significant things to be done and done wrong.[52]

Medical errors can be grouped into three general categories in terms of the human agents responsible for errors and their correction within institutions: 1) individual deficiencies; 2) system deficiencies; and 3) team deficiencies.

1. Individual Deficiencies

These can be momentary lapses or long-term failures of technique or education in the health care setting, psychological or education deficits being viewed as the culprit. Malpractice litigation is physician-specific, a hunt for deviations from a standard of care or a failure in a particular case that causes a bad patient outcome. Medical discipline likewise focuses on the individual physician and her deviation from acceptable practice in the state in which she is licensed. Studies not surprisingly have found that physicians are generally more often responsible for such errors than are nurses, pharmacists or other hospital personnel.[53] The response at least to

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[50] J.W. Senders, *Medical Devices, Medical Errors, and Medical Accidents*, in HUMAN ERROR IN MEDICINE 170-71 (Marilyn Sue Bogner ed., 1994).

[51] *Id.* at 170.

[52] *Id.* at 170-71.

[53] *See* David W. Bates, et al., *Incidence and Preventability of Adverse Drug Events in Hospitalized Patients*, 8 J. GEN. INTERN. MED. 289 (1993) (reporting findings of a study which evaluated the incidence and preventability of adverse drug events (ADE's) and found that ADE's

drug related errors has been individual strategies such as computerized order entry to eliminate errors from poor handwriting.[54] Individual deficiencies are an important aspect of error reduction, since education and training can eliminate some of these problems. A system focus still means professional re-education, training, and dissemination of clinical guidelines and evidence-based medicine.[55]

2. System Deficiencies

The current debate over medical errors has shifted critical discussion toward the health care delivery system—typically the hospital—and away from individual providers. The work of Charles Perrow has stimulated the work of medical researchers in this direction.[56] Perrow developed a distinction between tightly coupled systems where "normal" accidents are predictable; and loosely coupled systems, which tends to characterize the hospital settings.[57] Loosely coupled systems allow more flexibility for error detection and prevention; in such systems "near misses" are useful tools for preventing patient injury as error prevention pathways are developed.[58] One problem with the current enthusiasm for systems fixes is that hospital organizational systems are highly resistant to change and linear fixes.[59] Hospitals have to commit financial and staff resources to error prevention, and they have completing pressures on them.[60] As Howard Burde writes,

> [h]ealthcare providers generally dislike data collection and submission because it is a time-consuming, expensive, and unproductive

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were primarily the result of physician error as opposed to errors by nurses or pharmacy staff).

[54] *See generally* Larry I. Palmer, *Patient Safety, Risk Reduction, and the Law*, 36 HOUS. L. REV. 1609 (1999) (discussing how system approaches can improve health care safety and efficiency).

[55] *See generally* Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?* 25 AM. J. L. & MED. 403 (1999) (discussing the benefits of clinical practice guidelines and the forces that make some physicians resistant to change).

[56] *See* Amy C. Edmondson, *Learning From Mistakes Is Easier Said Than Done: Group and Organizational Influences on the Detection and Correction of Human Error*, 32 J. APPLIED BEHAV. SCI. 5, 8 (1996) (discussing the theories of sociologist, Charles Perrow).

[57] *Id.*

[58] *Id.*

[59] "Much physician resistance to guidelines and formulas, anything that can be characterized as cookbook medicine, derives from this perspective of autonomy and virtuosity." Furrow, *supra* note 55, at 414.

[60] *See* Howard Burde, *The Implementation of Quality and Safety Measures: From Rhetoric to Reality*, 35 J. HEALTH LAW 263, 274 (2002).

exercise with no discernable direct benefit. The challenge for gov-
ernments is to limit the cost and potential liability inherent in the
collection and submission of data, and to ensure the narrow focus
and utility of the data to be collected.[61]

I would extend Burde's observations a step further. Govern-
ment must first mandate data collection and mandatory reporting of
medical mistakes of all kinds, so that all hospitals have incentives to
respond and face similar risks for failing to do so. Limiting the cost
and liability is a proper regulatory consideration, but the goal of
mandating collection and disclosure of errors is the primary one.

3. Team Deficiencies

Hospitals are not top-down hierarchical bureaucracies. To the
contrary, they are loosely coupled in several ways: the medical staff
has authority independent of the hospital administration; nurses
and other allied providers are employees of the hospital; and hospi-
tal pharmacies have often been poorly integrated into patient care.
The process by which physicians and other providers learn about
new clinical findings, sources of error and other technologies is not
a straightforward linear one.[62] One suggestion therefore has been to
focus on teams within organizations, to view them as "self-cor-
recting performance units."[63]

Edmondson describes a "superb team" as one that has the abil-
ity to "perform as a seamless whole."[64] Error rates vary across such
units even within the same hospital.[65] In one study, unit error rates
in a drug complication study ranged from 2.3 to 23.7 errors per
thousand patient days.[66] The study found that "a primary influence
on detected error rates is unit members' willingness to discuss mis-
takes openly."[67] Edmondson writes that,

> [l]eadership behavior influences the way errors are handled, which
> in turn leads to shared perceptions of how consequential it is to
> make a mistake. These perceptions influence willingness to report
> mistakes, and may contribute to a climate of fear or of openness

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[61] *Id.*

[62] *See* Martin Wood, et al., *Achieving Clinical Behavior Change: A Case of Becoming Indetermi-
nate,* 47 Soc. Sci. Med. 1729, 1729 (1998) (noting that transfer of evidence based medical
research is not linear and "may underestimate the impact of other confounding
circumstances").

[63] Edmondson, *supra* note 56, at 9.

[64] *Id.*

[65] *Id.* at 11

[66] *Id.*

[67] *Id.* at 24.

that is likely to endure and further influence the ability to identify and discuss problems.[68]

I believe it is even more complicated than this. Errors in the operating room originate in the backgrounds of the participants, within group dynamics and the environmental settings.[69] To focus on the cause of an error, one must consider the social context of the specific behavior causing the mistake, including the organizational and physical dynamics.[70]

Factors that foster the making of errors in the health care setting are most likely different from factors that foster detecting, correcting, discussing and learning from errors. The leader of teams and units within hospitals has a critical role in error reduction. Edmondson observes that "willingness to report errors varies systematically with perceived openness of unit leaders, and we can speculate that these attributes may overwhelm differences in actual error rates."[71]

Many errors are simply never reported.[72] Reasons may include failure to recognize that an error occurred, liability worries, concerns about job security (nurses), and concerns about personal and professional reputation.[73] One study found that 29% of observed errors were not reported. Organizational embracing of error disclosure is essential through rewarding disclosure of errors by teams.[74] Thus, to foster an environment in which more errors are reported we must create work environments in which there in a strong emphasis on learning from mistakes. But given that most errors are not reported, it is not clear how a voluntary system can contribute to error detection and disclosure. Only a mandatory system of detection and disclosure can lead to effective error correction.

Health care has become a large-scale, corporate, team-oriented enterprise, no surprise in light of the complexity of modern medicine and the rate of new findings from clinical research as to what works and what doesn't. And yet these enterprises are often chaotic and poorly managed, producing far too many errors that

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[68] Edmondson, *supra* note 56, at 24.

[69] ROBERT L. HELMREICH & HANS-GERHARD SCHAEFER, *Team Performance in the Operating Room,* IN HUMAN ERROR IN MEDICINE 225, 226 (Marilyn Sue Bogner, ed., 1994)

[70] *Id.*

[71] Edmondson, *supra* note 63, at 24.

[72] MARGARET H. APPLEGATE, *Diagnosis-Related Groups: Are Patients in Jeopardy?,* in HUMAN ERROR IN MEDICINE 349, 356 (Marilyn Sue Bogner, ed., 1994).

[73] *Id.*

[74] *Id.*

injure patients. A careful reading of recent cases finds failures of institutions to effectively deliver care, as team delivery manifests a range of failures.[75] And while individual providers can be faulted, what is more common is the failure of a system, and units within the system, to avoid an otherwise avoidable error.[76] The hospitals described in many recent malpractice cases lack good management—they are far from the industrial model of continuous quality improvement. The very structure of delivery through a medical staff working with hospital employees like nurses creates a diffusion of authority, which results in failure to communicate.[77] And the training of residents by attending physicians often produces errors through failures to adequately supervise beginners in the field.[78] Consider the following cases and frequent judicial invocation of "team" failures in imposing liability.

Institutional complexity requires accountability: a person must be in charge, often the attending physician in situations where residents are part of the care.[79] In *Lownsbury v. VanBuren*, the parents sued a teaching hospital's attending physician for the injury to their adopted daughter who was born with severe brain damage, and for the prenatal care provided to the biological mother by the residents.[80] The supervisory physician had a duty to be familiar with the patient's condition, to review tests by and formulate a treatment plan.[81] In that case, the supervising physician failed to review a portion of a test that revealed fetal distress.[82] The court quoted *Mozingo*

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[75] This article will consider the following cases in detail: Nold *ex rel.* Nold v. Binyon, 31 P.3d 274 (Kan. 2001); Hoffman v. East Jefferson Gen. Hosp., 778 So.2d 33 (La. Ct. App. 2001); Siebe v. Univ. of Cincinnati, 766 N.E.2d 1071 (Ohio Ct. Cl. 2001); Jennison v. Providence St. Vincent Med. Ctr., 25 P.3d 358 (Or. Ct. App. 2001); Rauch v. Mike-Mayer, 783 A.2d 815 (Sup.Ct. Pa. 2001).

[76] *See, e.g., Nold*, 31 P.3d at 274 (holding that doctors and hospital were liable for hepatitis B transmission to a baby when they failed to notify the mother of her positive status); *Jennison*, 25 P.3d at 358 (holding doctors and hospital liable for patient's death when the placement of her central line was not checked after surgery).

[77] *See generally* Barry R. Furrow, *Enterprise Liability and Health Care Reform: Managing Care and Managing Risk*, 39 St. Louis L.J. 77 (1994) (discussing the evolving complexities of health care organizations).

[78] *See, e.g., Siebe*, 766 N.E.2d at 1073 (holding doctors and hospital liable for patient's death when a resident inserted a central line without supervision).

[79] Lownsbury v. Van Buren, 762 N.E.2d 354 (Ohio 2002).

[80] *Id.* at 355.

[81] *Id.* at 356-57.

[82] *Id.* at 355.

v. Pitt County Memorial Hospital, Inc., a similar case of on-call super-
vision of obstetrics residents at a teaching hospital:

> The modern provision of medical care is a complex process becom-
> ing increasingly more complicated as medical technology advances.
> Large teaching hospitals. . . .care for patients with teams of profes-
> sionals, some of whom never actually come in contact with the
> treated patient but whose expertise is nevertheless vital to the treat-
> ment and recovery of patients.[83]
> Unlike the traditional personalized delivery of health care, where
> the patient seeks out and obtains the services of a particular physi-
> cian, the institutional environment of large hospitals incorporates a
> myriad of complex and attenuated relationships. Here the present-
> ing patient enters a realm of full-service coordinated care in which
> technical agreements and affiliations proliferate the specialized
> functions and obligations of various allied health professionals.[84]

Surgeons are in some states still the "captain of the ship" while
supervising others during surgery[85] they have the responsibility of
getting a patient's consent[86] as a part of joint management of many
patients.[87] Nurses are also viewed by courts as having independent
obligations to monitor and treat patients, and inform the treating
physicians as needed.[88] They may even have to fight for the patient
when a patient is about to be discharged with "unexplained and
unaddressed symptoms."[89]

II. LIMPING TOWARD SYSTEMS MANAGEMENT: BUMBLING
HEALTH CARE ENTERPRISES

> [C]ompassion and technology aren't necessarily incompatible; they
> can be mutually reinforcing. Which is to say that the machine,
> oddly enough, may be medicine's best friend. On the simplest
> level, nothing comes between patient and doctor like a mistake.
> And while errors will always dog us–even machines are not per-
> fect—trust can only increase when mistakes are reduced. Moreo-

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[83] *Id.* at 359 (quoting 415 S.E.2d. 341 (N.C. 1992)).

[84] *Lownsbury*, 762 N.E.2d. at 360 (quoting 415 S.E.2d 341 (N.C. 1992)).

[85] *See, e.g.*, Frasier v. Hanson, No. B143936, 2001 WL 1344040, at *1 (Cal.App. 2 Dist. 2002)
(imputing negligence to supervising physician even though resident performed
procedure).

[86] *See* Jacobo v. Binur, 70 S.W.3d 330, 334 (Tex. Ct. App.—Waco 2002) (holding that the duty
to get consent lies with the doctor treating the patient or performing the procedure).

[87] *See* Bynum v. Magno, 125 F.Supp.2d 1249, 1256 (D. Hawaii 2000) (holding that doctor, as
part of joint management, retains control over patient).

[88] *See* Brandon HMA, Inc. v. Bradshaw, 809 So.2d 611, 613 (Miss. 2001) (holding nursing staff
responsible for reporting "vital" information to treating physician).

[89] *See* Rowe v. Sisters of Pallottine Missionary Soc'y, 560 S.E.2d 491, 494 (W.Va. 2001) (hold-
ing nurses responsible for breaching the standard of care by not addressing symptoms of
patient and then discharging him).

ver, as "systems" take on more and more of the technical work of medicine, individual physicians may be in a position to embrace the dimensions of care that mattered long before technology came–like talking to their patients.[90]

The language of Continuous Quality Improvement and Total Quality Management of business management and the new JCAHO rules on hospitals suggest that the good aspects of the industrial model are being applied to hospitals.[91] The problem with health care delivery is not just that patient care is complicated, it is rather that institutional inertia seizes hospitals as they struggle for revenue in tough health care markets and this makes change difficult. Hospitals need sources of external pressure to induce institutional change.

I will use several new malpractice cases to provide a detailed description of hospital failures to avoid medical errors that caused severe harm to patients. These cases are useful both to illustrate the courts' growing impatience with hospital errors and to provide a more textured understanding of the complexities of the hospital setting and the need to mandate an effective approach to management of care within hospitals.

A. Team Coordination

A good health care team is a complex entity, marked by strong coordination and trust among team members. There are successful teams and poor teams. One example of team (and hospital) shortcomings is illustrated by *Hoffman v. East Jefferson General Hospital*.[92] In that case the plaintiff was admitted to East Jefferson hospital for two surgical procedures: a hysteroscopy with endometrial ablation and a laparoscopic cholecystostomy to be performed under anesthesia.[93] During the first procedure, the plaintiff was prepped and draped, and before the surgery, a speculum was inserted.[94] This speculum was sterilized per protocol in an autoclave at 273 degrees for seven to ten minutes before being brought into the operating

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[90] ATUL GAWANDE, *supra* note 26, at 45.

[91] *See generally* Timothy S. Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825, 838 (1995) (citing R. Heather Palmer & Mary M.E. Adams, *Quality Improvement/Quality Assurance Taxonomy: A Framework*, in PUTTING RESEARCH TO WORK IN QUALITY IMPROVEMENT AND QUALITY ASSURANCE 13, 17 (1993)).

[92] 778 So.2d 33 (La. Ct. App. 2001).

[93] *Id.* at 34.

[94] *Id.* at 35.

room and set on a sterile table to cool.[95] In this case, however, the doctor did not allow sufficient time for the instrument to cool before using it on the patient.[96] After both procedures were performed, the plaintiff was brought to the recovery room where blisters were noticed on her buttocks.[97] The plaintiff suffered third degree burns, which required surgical debridement and skin grafting.[98] The doctor described the event as a "freak accident," but noted that, while he was indeed responsible for the patient's care and directed the nurses and technicians, the cause of the accident was "multi-factorial, with a lot of people having some responsibility."[99]

Consider the overlapping and coordinated responsibility. Nurses are responsible for sterilizing the instruments and cooling them before use.[100] A nurse told the doctor that the instrument might still be warm, but the doctor did not allow more time for it to cool.[101] The hospital contended that it was the doctor's responsibility to check the temperature.[102] The court disagreed, finding that,

> [T]he use of an instrument before it is sufficiently cooled after sterilization is a breach of the standard of care both for hospital employees and the doctor performing the surgery. . . .it was the responsibility of all members of the surgical team, whether hospital employees or independent doctors, to make sure the instruments are cool.[103]

The court noted that the doctor and all of the surgical staff who assisted him had failed to use reasonable care and diligence in not waiting for the instrument to cool sufficiently, or even checking to see if in fact it had cooled.[104] In other words, it was a team failure, a failure of policy, the kind of mistake that can easily be prevented with proper procedures. It was a simple mistake, with catastrophic results for a patient. And both the doctor, as a member of the medical staff, and the nurses, as hospital employees, were responsible.

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[95] Id.

[96] Id. at 42.

[97] Hoffman, 778 So.2d at 42

[98] Id.

[99] Id. at 36.

[100] Id. at 35.

[101] Id. at 40.

[102] Hoffman, 778 So.2d at 41.

[103] Id.

[104] Id. at 42.

The court looked behind legal forms to impose responsibility on the operating team to non-negligently take care of the patient.[105]

B. Coordination of Treating Physicians

The current health care system often requires coordination of primary care physicians, specialists, and other hospital physicians over an extended period of time when a patient is undergoing treatment.[106] The accurate transmission of patient information to these levels of providers is therefore critically important, and if a provider misses a critical piece of information, the result can be devastating.[107] In *Nold v. Binyon*, a baby was injured because of the failure of doctors and a hospital to notify the mother of her hepatitis B status and to administer gamma globulin and vaccine treatment to the baby at the time of her birth or soon thereafter.[108] The procedure called for a physician to send a patient's prenatal records to the delivering hospital at about 34 to 36 weeks' gestation to be filed as the records came into the unit.[109] According to testimony, "[w]hen the patient was later admitted to the hospital, the unit clerk would retrieve the patient's prenatal history from the filing cabinet, put it with the chart that was being assembled upon admission, and deliver the chart to the physician who was handling the labor and delivery."[110]

These records would be stamped within a chart with "address-o-graph" information.[111] The address-o-graph stamp included the patient's hospital stay number, name, birthday, date of admission, and the date the record was received.[112]

> This procedure ensured that such information was on every piece of permanent record within the hospital and that the information would follow the patient through the course of her care and treatment at Wesley. Bonnie's prenatal records from Dr. Moser were stamped with an address-o-graph, showing that Wesley received the records. However, the only date that appeared in the address-o-graph information was Bonnie's September 14, 1990, admission date. At trial, Wesley personnel testified that, despite the professed

[105] *See id.* at 42-43.

[106] *See generally* Nold *ex rel.* Nold v. Binyon, 31 P.3d 274 (Kan. 2001).

[107] *Id.*

[108] *Id.* at 277.

[109] *Id.*

[110] *Id.* at 279.

[111] *Nold*, 31 P.3d at 279.

[112] *Id.*

practice of stamping records with the date they are received, the information concerning the receipt of the records is inaccurate and unreliable.[113]

The standard practice when a baby was born was to place information in the mother's medical chart for the baby.[114]

> Dr. Moser expected the standard practice to occur in Bonnie and Audra's case. He assumed that the hepatitis B information would find its way in a timely manner to the appropriate caregivers for Audra, including her designated pediatrician. The pediatrician could then provide Audra with appropriate care and treatment to prevent hepatitis B transmission.[115]

The record transfer system failed to put the sequence of treating physicians on notice of a clinical finding that would have triggered Hepatitis B treatment.[116] What followed was a series of failures with catastrophic results: failures to review the records, to coordinate care, and to inform subsequent caregivers of the mother's Hepatitis B status so the newborn could receive a timely injection of gamma globulin.[117] The coordination of physicians was poor in this situation; the information in the patient's transferring records was inaccurate.[118] A poor system created a recipe for a disaster that could easily have been averted.

C. Lack of Policies

If health care is a complex system in need of coordination, then policies are essential to coordinate care. Both the medical error literature and the systems approach to quality agree on the need for overall coordination of care within complex systems. The following considers the disasters that can occur in the absence of such policies.

1. Deficiencies in Follow-Up Policies

In *Jennison v. Providence St. Vincent Medical Center*, a patient suffered severe brain injury while recovering from surgery.[119] In that case, the patient was a forty-five year-old woman with a history of abdominal pain who was found lying on the floor of her home in

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[113] *Id.*

[114] *Id.* at 280.

[115] *Id.*

[116] *Nold*, 31 P.3d at 280-281.

[117] *Id.*

[118] *See id.*

[119] Jennison v. Providence St. Vincent Med. Ctr., 25 P.3d 358, 361 (Or. Ct. App. 2001).

severe pain.[120] She was taken to the emergency room of the hospital, admitted for diagnosis, and tested to determine the source of the problem.[121] After several days of diagnostic uncertainty, the physicians considered an exploratory laparoscopy, suspecting an abnormality in her small intestine.[122]

Before surgery an anesthesiologist inserted a central venous catheter (central line) in the patient.[123] She then underwent surgery, and her right fallopian tube and ovary were removed because of infection.[124] She was taken to the Post Anesthesia Care Unit (PACU) with the central line still in place.[125] A surgical resident assisting the treating physician wrote the post-operative orders, which included a chest x-ray to check the placement of the central line.[126] The patient continued to have pain and was given pain medications.[127] Finally, the x-ray, taken four hours earlier, was checked and it revealed that the central line was inserted incorrectly, and the tip had punctured the pericardial sac of the patient's heart.[128] While the doctors were able to successfully resuscitate her, the patient experienced a cardiac tamponade, in which her heart was crushed by fluid pressure, leading to cardiac arrest.[129] She ended up with severe brain injury.[130]

The hospital lacked policies and procedures for follow-up on central lines placed in the OR when a patient is transferred to the PACU.[131] The court noted that the call from radiology could potentially go to one of five different people, depending on whom the radiologist decides to call.[132] Moreover, written documentation was not required of anyone who might receive the call from radiology, so no one else would know whether the call was ever actually

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[120] *Id.* at 360.

[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] *Jennison*, 25 P.3d at 358.

[125] *Id.*

[126] *Id.*

[127] *Id.* at 360-361.

[128] *Id.* at 361.

[129] *Jennison*, 25 P.3d at 361.

[130] *Id.*

[131] *Id.* at 361-362.

[132] *Id.* at 363.

made.[133] So while the hospital's policy and procedure required verification, no policy controlled subsequent staff actions.[134] A failure of coordination again allowed an avoidable patient disaster to occur.[135]

2. Failures in Surgical Approval Policies

A second example of poor hospital policy, illustrated by *Rauch v. Mike-Mayer*, involves a defective surgical policy.[136] In that case, the patient fell and severely injured her elbow.[137] The Emergency Department of the Mercy Regional Health System diagnosed her with a fractured olecranon process, and referred her to an orthopedic surgeon.[138] The surgeon examined the patient, and scheduled her for corrective surgery the following day.[139] The doctor noted that she had a medical history of "hypertension, diabetes mellitus, two myocardial infarctions with quadruple bypass surgery and a cerebrovascular accident affecting her left side."[140] She was taking numerous medications, she smoked a pack of cigarettes per day and abnormal chest x-rays suggested congestive heart failure.[141] An EKG indicated ischemic heart disease and signs of edema suggested congestive heart failure.[142] She was a dreadful candidate for any kind of surgery.[143] And, in fact, after the anesthesia was administered, she deteriorated rapidly, had cardiopulmonary failure and stroke, and died a few days later from complications of the stroke.[144] The anesthesia was the cause of her death, as she was severely "medically compromised" and an elbow operation did not justify the obvious risks.[145] The court concluded that the hospital has a duty to a patient to mandate medical clearance before a procedure is

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[133] *Id.*

[134] *Jennison*, 25 P.3d at 363

[135] *See id.* at 362.

[136] Rauch v. Mike-Mayer, 783 A.2d 815 (Sup.Ct. Pa. 2001).

[137] *Id.* at 818.

[138] *Id.*

[139] *Id.*

[140] *Id.*

[141] *Rauch*, 783 A.2d at 818-19.

[142] *Id.*

[143] *Id.* at 826.

[144] *See id.*

[145] *Id.* at 825.

done, and to force consideration of all options, including doing nothing.[146] Frustration with lack of control and oversight over a member of the medical staff is apparent here, as the uncoordinated hospital setting again causes an avoidable bad result.[147]

3. Failures of Supervision

In *Siebe v. University of Cincinnati*, the patient, Donna Siebe developed end-stage renal failure, necessitating a kidney transplant.[148] The patient's brother, was a suitable kidney donor.[149] The patient and her brother arrived at the defendant hospital and preparations were made for the two surgeries.[150] The first surgery was to remove the left kidney of the donor; the second was to implant it into Mrs. Siebe.[151]

> Dr. Janet Torpy, the attending anesthesiologist, was scheduled to insert a central venous line ("CVL") into Donna's right jugular vein. At the time of the surgery, Dr. Torpy was called away to an emergency and left the operating room. Dr. Dirk Younker, a staff anesthesiologist, began preparations for insertion of the CVL but he too was called to an emergency. Dr. Elizabeth Burgess, another staff anesthesiologist, was also called to an emergency. Dr. Burgess asked Dr. Lynda Groh, an anesthesia resident, to help make sure that the CVL was properly placed. When Dr. Groh entered the operating room, she was told to assist Lennda Hungerford, a trainee nurse anesthetist. Hungerford inserted the CVL in the presence of Dr. Groh. Hungerford testified that she had never placed a CVL, and that she did not have any formal training regarding the placement of a CVL.[152]

Neither the resident nor the trainee nurse anesthetist was authorized by the hospital to insert a CVL without the supervision of a staff anesthesiologist.[153]

The transplant was successful, and Donna was sent to the post-anesthesia care unit ("PACU") in stable condition for observation and care. At 3:30 p.m., a chest x-ray was taken to confirm the position of the CVL, which is standard procedure. Dr. Frans Rahausen, the surgery fellow who assisted Dr. Wesley Alexander in transplanting the kidney into Donna, reviewed the x-ray and requested that

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[146] *Rauch*, 783 A.2d at 825.

[147] *Id.*

[148] Siebe v. Uni. of Cincinnati, 766 N.E.2d 1070, 1073 (Ohio Ct. Cl. 2001).

[149] *Id.*

[150] *Id.*

[151] *Id.*

[152] *Id.*

[153] *Siebe*, 766 N.E.2d at 1075.

the anesthesia department be called to pull back the line because it appeared that the CVL was in too far.[154]

The CVL had gone into her chest.[155] At this point, another doctor said he would adjust the line, but never returned to do so.[156] The patient's blood pressure dropped dangerously low and her heart raced; a "code" was called and CPR began.[157] Her blood pressure dropped further and she died soon after.[158]

The hospital failures were several: allowing a trainee to place a line without proper supervision and failing to follow-up on the proper placement of the CVL after it was discovered to be improperly placed.[159] The question of who is in charge looms large in this case, as poorly coordinated care again led to disaster.[160]

These malpractice cases are valuable because they ventilate medical errors, forcing a hard look at errors that we often do not get a chance to see, given the self-protective instincts of physicians and hospitals. They strip away the concealment that marks many institutional errors, and reveal the tip of an iceberg: that hospitals are dangerous places often because systems function poorly and teams fail in coordinating care to minimize risks to patients.

III. THE PATH TO ERROR REDUCTION: EXCAVATION OR VENTILATION?

Error reduction requires information on cases of both near misses and serious adverse events. Too often the search for causes of bad outcomes resembles an archeological excavation: a labored search for hidden treasures buried under layers of distracting material, requiring meticulous and time-consuming digging. It is work done by lawyers with all the tools of civil discovery at hand. Excavation, however, is not a model that works in health care institutions, since waiting for the plaintiff's lawyer with a bad outcome in hand is too late and uncovers only a tiny fraction of total errors that occur. A ventilation model is preferable when errors and near misses are transparent to the actors in the system, and to those that

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[154] *Id.* at 1073-1074.

[155] *Id.* at 1074.

[156] *Id.*

[157] *Id.*

[158] *Siebe,* 766 N.E.2d at 1074.

[159] *Id.* at 1073-74.

[160] *Id.*

manage the system. Errors must be reported and evaluated before change can be implemented. In the case studies I discussed above, the litigation may well have spurred focused change in the institutions to avoid a repeat of these particular errors. It induces at best a retrospective review and reaction to a particular disaster. However, hospital management of its systems is loosely coupled, without sufficient reflection prospectively as to flaws that might result in errors. Forces of medical staff autonomy, inertia and lack of resources and time in nursing create barriers to error reporting or efforts toward systematic improvements to reduce errors.

IV. THE MERITS OF MANDATORY REPRINTS OF ERRORS

The issue of mandatory versus voluntary reporting has loomed large for health care providers, afraid that disclosure of an error will come to plaintiff lawyers' attention. Recommendation 5.1 of the Institute of Medicine report calls for mandatory reporting by hospitals and other institutions of "adverse events that lead to death or serious bodily harm."[161] Critics worry that this may drive honest disclosure even further underground, deterring providers from revealing errors. The only study to date of error reporting systems found that there was little difference between systems that provided confidentiality and those that did not.[162] Underreporting occurred in both systems at about the same levels.[163]

Voluntary reporting of mistakes has been argued to be the preferable approach to uncovering errors and correcting them.[164] Bryan Liang argues that,

> [v]oluntary reporting is the preferable method of encouraging providers to report errors due to its cooperative nature; however, politically, there may be calls for mandatory reporting. It is hoped that the poor experience with mandatory reporting would be instructive for those who pin their hopes on requiring errors and associated adverse events to be reported for patient safety.[165]

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[161] See Reports and Publications on Medical Error, Patient Safety, available at http://voice4patients.com/reports.htm (last visited March 23, 2003).

[162] See State Reporting of Medical Errors and Adverse Events: Results of a 50-State Survey, Executive Summary, available at http://www.nashp.org/_docdisp_page.cfm?LID=0560704C-4CAC-11D6-BCEE00A0CC558925. (last visited March 23, 2003) [hereinafter 50-State Survey].

[163] Id.

[164] Bryan A. Liang, The Adverse Event of Unaddressed Medical Error: Identifying and Filling in the Holes in the Health-Care and Legal System, J.L. MED. & ETHICS 346, 358 (2001).

[165] Id. at n. 176.

It might be, however, that this poor experience with mandatory reporting is largely due to the fact that it is not truly mandatory, too easily allowing providers to avoid reporting without fear of sanctions.

States that have mandatory reporting requirements for errors have found that underreporting is the norm.[166] But the fact that underreporting occurs does not mean that performance cannot be improved. The reasons for such poor performance are several. As Leape writes:

> Despite calls for increased accountability on the part of hospitals and the availability of the National Quality Forum's standardized list of serious reportable events, mandatory systems appear to lack a major constituency in most states and therefore fail to receive adequate financial support. Unless that changes, mandatory reporting systems are likely to remain relatively ineffective.[167]

If you add fear of liability, damage to reputation, and the hassle factor of any reporting system, then it is clear that physician resistance in particular has a multiplicity of sources.

Mandatory error reporting has several advantages. First, institutional incentives are enhanced by mandated error reporting.[168] The health care institution has incentives to better track and monitor errors within its walls if required to report at the risk of sanctions.[169] Risk management may be turned into something more than a legal backwater driven by insurance considerations if mandatory reporting becomes the norm for hospitals and other institutions.[170] Assuming that the various mandates have some regulatory teeth, a hospital risks sanctions for its failure to comply; patients learn about errors, and the ventilation of error and the transparency of the processes expose variations among providers.[171]

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[166] See 50-State Survey, supra note 162.

[167] Error in Medicine, supra note 14, at 1638.

[168] Melissa Chiang, Note, Promoting Patient Safety: Creating a Workable Reporting System, 18 YALE J. ON REG. 384 (Summer 2001), (citing the argument that mandatory reporting systems provide an incentive for institutions to pay more attention to safety issues in order to avoid public exposure).

[169] LINDA T. KOHN, JANET M. CORRIGAN, ET AL., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 86 (2000).

[170] Id. at 11.

[171] Id. (stating the actions of consumers and purchasers of health care affect the behaviors of health care organizations).

Second, learning can only happen if root causes are understood.[172] The acknowledgment of near misses and patient injury—that an "error" occurred—is a major part of facilitating learning among individual providers as well as institutional providers.[173] The retreat from blame also risks retreat from responsibility: by neutering the climate of blame, we also weaken a culture in which providers challenge each other to improve. Patients appear to prefer honesty and apology when they have suffered an adverse event, and are less inclined to use litigation as a blaming mechanism, once they have been satisfied that the institution is attentive to error creation and correction.[174]

Third, voluntary reporting is unlikely to function effectively as an alternative to the feared results of mandatory reporting. Providers dread taking responsibility for error, as we would expect highly trained professionals to feel; a "mea culpa" does not come easily in a culture of perfection developed through medical training over many years.[175] If the law does not mandate reporting, and if the tort system were replaced tomorrow by a toothless compensation system free of trial lawyers, we would still be unlikely to see a blossoming of error reporting and a broadcasting of error admission by providers. Good intentions without financial and regulatory incentives to report are unlikely to succeed.[176] Voluntary reporting is unlikely to prove any more effective than mandatory reporting without a complete retooling of incentives.

Fourth, mandatory reporting will reshape leadership within institutions, acknowledging the centrality of error reduction and system failures as intolerable.[177] The connection between disclosure of errors and their correction is primarily fostered by the leadership climate in a health care institution, as Edmundson's research has

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[172] *Id.* at 63 (discussing elements in human factor analysis which helps to better understand what goes wrong in systems).

[173] *Id.* at 22 (discussing how liability concerns discourage the surfacing of errors and communication about how to correct them).

[174] *See generally,* Harold J. Bressler, *Safety Issues as Exemplified by the Activities of the Joint Commission on Accreditation of Healthcare Organizations: Context for the Safety and Disclosure Standards,* J. HEALTH LAW 179 (2002).

[175] *Error in Medicine, supra* note 14, at 1951.

[176] Jeffrey O'Connell and Patrick B. Bryan, *More Hippocrates, Less Hypocrisy: "Early Offers" As a Means of Implementing the Institute of Medicine's Recommendations on Malpractice Law,* 15 J.L. & HEALTH 23, 35 (2000/2001) (stating the IOM urges that legal reform is necessary in order to ensure that any reporting system, voluntary or mandatory, be effective).

[177] KOHN, ET AL., *supra* note 169, at 6 (discussing how leadership can encourage a culture of learning form mistakes).

proved.[178] Errors and near misses require institutional attention as well, since many mistakes may be due to staffing, resource limitations, poor leadership, and deterioration in skill that peers have not yet detected or are not yet willing to respond to.[179] A focus on teams within health care systems will facilitate the kind of learning and adaptation that can promote error reduction.

V. MOVING TOWARD A MANDATORY MODEL: REGULATORY PERMUTATIONS

Mandatory reporting is resisted by providers.[180] The emphasis has therefore been on voluntary reporting systems. But given the lack of evidence that such voluntary systems reveal most errors, a mandatory model should be developed.[181] Several moves in this direction are worth noting: the JCAHO Sentinel Events policy,[182] the new CMS rules on hospital error,[183] and the new Pennsylvania statute that requires disclosure of errors.[184]

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[178] *See* Edmondson, *supra* note 56 (stating that willingness to report errors varies systematically with perceived openness of leaders).

[179] KOHN, ET AL., *supra* note 169, at 60 (discussing more than just the need for good managerial skills to create a safe environment).

[180] Liang, *supra* note 32, at 348 (observing that stiff provider resistance to JCAHO's approach and other mandatory reporting systems has contributed to a system that catches less than one percent of the errors).

[181] KOHN, ET AL., *supra* note 169, at 156 (2000) (Recommendation 8.1 of the IOM Report, To Err is Human, supra n states:

Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should

* provide strong, clear and visible attention to safety;

* implement non-punitive systems for reporting and analyzing errors within their organizations;

* incorporate well-understood safety principles, such as, standardizing and simplifying equipment, supplies and processes; and

* establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.)

[182] JCAHO, "Sentinel Event Policy and Procedures," *available at* http://www.jcaho.org (last visited Jan. 28, 2003).

[183] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified at 42 C.F.R. pt. 482).

[184] Medical Care Availability and Reduction of Error (Mcare) Act. PA, STAT, ANN. Tit 40, § 1303.303 (2002).

A. Glacial Standard Setter: The Joint Commission on the Accreditation of Healthcare Organizations

The JCAHO is a private accreditor, granted authority by federal and state governments to accredit hospitals.[185] The new JCAHO Sentinel Event Policy has adopted the view of medical errors found in the Institute of Medicine report *To Err is Human*.[186] It requires reporting on two levels: first to JCAHO of serious events, and second to patients.[187] It defines a sentinel event as "an unexpected occurrence involving death or severe physical or psychological injury, or the risk thereof," including unanticipated death or major loss of functioning unrelated to the patient's condition; patient suicide; wrong-side surgery; infant abduction/discharge to the wrong family; rape; and hemolytic transfusion reactions.[188] Hospitals must report serious events to the JCAHO, and if they do not and JCAHO learns of the events form a third party, the hospital must conduct an analysis of the root cause or risk loss of accreditation.[189] Loss of accreditation is rarely exercised, however, leaving accreditation as a modest tool to promote uniformity of hospital systems.[190]

The JCAHO disclosure standard also requires that "[p]atients, and when appropriate, their families, are informed about the outcomes of care, including unanticipated outcomes."[191] The intent statement provides: "The responsible licensed independent practi-

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[185] *See generally* Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Health Relationship?* 57 LAW & CONTEMP. PROBS. 15(1994); Timothy Stoltzfus Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C. L. REV. 835, 882 (1983); Eleanor Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When Is It Appropriate?*, 57 J. LAW & CONTEMP. PROBS. 47, 52-55 (1994); Douglas C. Michael, *Federal Agency Use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171, 218-22 (1995).

[186] *See* INSTITUTE OF MEDICINE, *supra* note 1.

[187] *Id.*

[188] JCAHO, "Sentinel Event Policy and Procedures", *available at* http://www.jcaho.org (last visited Jan. 28, 2003).

[189] Sentinel Event Alert, Joint Commission on Accreditation of Healthcare Organizations 2002, *available at* http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/index.htm (last visited Feb. 1, 2003).

[190] Ursula Weide, *Health Care Reform and the Changing Standard of Car in the United States and Germany*, 20 N.Y.L. SCH. J. INT'L & COMP. L. 249, 260 (2000) (stating JCAHO only revokes hospitals' accreditation in extreme cases).

[191] Joint Commission on Accreditation of Healthcare Organizations, Revisions to Joint Commission Standards in Support of Patient Safety and Medical/Health Care Error Reduction, *available at* http://www.jcaho.org/standard/fr_ptsafety.html (July 1, 2001) (JCAHO Revisions) at RI.1.2.2.

tioner or his or her designee clearly explains the outcomes of any treatments or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes."[192]

The JCAHO standard unfortunately suffers from several infirmities. First, the use of "significantly" is not self-defining, and hospitals are likely to adopt a very conservative interpretation to reduce their disclosure obligations.[193] JCAHO indicates that they are the same as "sentinel events" or "reviewable sentinel events." A "sentinel event" is defined in JCAHO standards as:

> an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.[194]

The second problem is the locus of the disclosure obligation. The intent statement specifies "the responsible licensed independent practitioner or his or her designee," who must clearly explain "the outcomes of any treatments or procedures."[195] This practitioner is someone with clinical privileges, typically the patient's attending physician.[196] Since the attending physician typically has the informed consent responsibility, he or she is the logical person to conduct such a conversation. But physicians are not subject to JCAHO requirements, and they are therefore likely to resist such disclosures out of fear of liability, stigma or other motivations.[197] LeGros and Pinkall note that

> [s]ome hospitals already have encountered resistance from medical staff members regarding involvement in the disclosure process. . .the Joint Commission has not issued guidance on what is to be done if the physician refuses to make the disclosure. The issue could be a particularly explosive one if the physician was responsible for the error.[198]

The disclosure of errors that lead to an increased number of small claims increases the risks to physicians. "The impact of multiple claims on professional credentialing matters likely is one reason

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[192] *Id.* (emphasis added).

[193] *See, e.g.,* Nancy LeGros and Jason D. Pinkall, *The New JCAHO Patient Safety Standards and the Disclosure of Unanticipated Outcomes,* 35 J. HEALTH LAW. 189, 191 (2002).

[194] *Id.* Joint Commission on Accreditation of Healthcare Organizations, Hospital Accreditation Standards 53 (2001).

[195] LeGros & Pinkhall, *supra* note 193, at 193.

[196] *Id.*

[197] *Id.*

[198] *Id.*

why many hospitals are encountering resistance from physicians in participating in the disclosure process."[199]

Third, private accreditation like that provided by JCAHO is notoriously gentle in its approach, slow to develop meaningful standards and reluctant to develop enforcement mechanisms other than the unlikely threat of withdrawal of accreditation.[200] The use of organizations like JCAHO has advantages, saving government money and offering a collaborative model of negotiated standard setting.[201] Swift and forceful regulation is not the hallmark of the JCAHO approach.

B. Reluctant Regulator: The New CMS Rules on Error

The Center for Medicare and Medicaid Services (CMS) has recently issued a final rule that requires hospitals to develop a quality assessment and performance improvement (QAPI) program.[202] This QAPI program is intended to push providers to look at the care delivered to their patients and how the hospital performs.[203] It mandates systematic examination of a hospital's quality and undertakes improvement projects on an ongoing basis, in order to maintain hospital quality of care at what CMS calls "acceptable" levels.[204] The Rules list the requirements as including the identification and verification of quality problems and their causes; acting to correct these deficiencies; and determining the success of an intervention; and detecting new problems.[205] "Performance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance."[206] Under a performance im-

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[199] *Id.* at 205.

[200] Barry R. Furrow, *Regulating the Managed Care Revolution: Private Accreditation and A New System Ethos*, 43 VILL. L. REV. 361 (1998); Michael J. Astrue, *Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation*, 57 LAW & CONTEMP. PROB. 75 (1994) .

[201] *See* Douglas C. Michael, *Federal Agency use of Audited Self-Regulation as a Regulatory Technique*, 47 ADMIN. L. REV. 171 (1995).

[202] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified at 42 C.F.R. pt. 482).

[203] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (listing the requirements for using data collected to monitor the effectiveness of services and quality of care and identify opportunities for improvement and changes that will lead to improvement).

[204] *Id.*

[205] *Id.*

[206] *Id.*

provement framework, hospitals will continuously study and improve the processes of healthcare and delivery of service.[207]

CMS notes in the summary of the Rules and review of the comments to the Proposed Rules that medical error in hospitals has become a major concern for patients and payors.[208] "While both the public and the private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed to further reduce these types of incidents."[209] "Therefore, we are publishing this final rule, with some modification in response to comments, to guide improved patient safety in the hospital setting."[210] The comments note that medical errors are sometimes hard to recognize due to patient variation, and providers may not notice that a product or procedure caused a problem, given an already sick patient.[211] Detection is difficult since "medical errors usually affect only a single patient at a time, they are treated as isolated incidents and little attention, if any, is drawn to these problems."[212] And errors are underreported.[213] "All of these factors explain the ongoing invisibility of medical errors despite the existence of research that documents their high prevalence."[214]

CMS has promulgated this new rule to follow up the IOM recommendations in their previous reports: reduction of preventable medical errors; a system of public accountability; a knowledge base system regarding medical errors; and a change in the culture of healthcare organizations to ferret out errors and improve patient safety.[215]

CMS notes that accreditation surveys for deemed status performed by national accrediting organizations such as JCAHO are performed under the authority of CMS, and may provide grounds for enforcement by CMS in some cases.[216] During accreditation surveys, CMS intends that their QAPI program will be evaluated for

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[207] *Id.*

[208] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3436.

[209] *Id.*

[210] *Id.*

[211] *Id.*

[212] *Id.*

[213] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3436.

[214] *Id.*

[215] *Id.*

[216] *Id.*

its "hospital-wide effectiveness on the quality of care provided."[217] If a hospital, for example is ". . .significantly out of compliance with the QAPI CoP requirements, the hospital will be scheduled for termination from the Medicare and Medicaid programs."[218] A plan of correction could then be submitted and a follow-up survey conducted to see if the hospital can bring itself into compliance.[219] The Quality Improvement Organizations (QIOs) (formally known as Peer Review Organizations (PROs)) are intended to be CMS's "quality improvement agents."[220]

What is the role of medical error reporting? Is a mandatory system required? CMS writes in the comments:

> We agree that hospitals should consider adverse events in the development of its QAPI strategy. We expect hospitals to implement an internal error reduction system. *Adverse event tracking and analysis of underlying causes are an effective way to determine issues involving medical errors.* [Italics mine]. We emphasize the need for hospitals to assess processes and systems that affect patient care and quality. Section 482.21(c) requires the hospital(s) to establish priorities, and identify areas of risk that affect patient safety. We believe that the identification of adverse events and analyses of events must be an integral part of the hospital's QAPI program, as the analyses will lead to better protections for patients.[221]

The standards of the Joint Commission are consistent with the CMS Rule, according to the Comments. Section 482.21(c) of the Rules requires hospitals to "consider prevalence and severity of identified problems and to give priority to improvement activities that affect clinical outcomes, patient safety, and quality of care."[222] JCAHO's sentinel events could be one such source, along with external industry data, or government data.[223] The current rules do not yet require evidence-based performance measures, which are left to a future rule-making process.[224] Nor is mandatory reporting re-

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[217] *Id.*

[218] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3436.

[219] *Id.*

[220] *Id.*

[221] *Id.* at 3435, 3438.

[222] *Id.* at 3435.

[223] The Agency for Healthcare Research and Quality (AHRQ) has been funding research and developing evaluative criteria on effectiveness and errors *available at* http:// http:// www.ahcpr.gov/qual/errorsix.htm.

[224] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3445 (January 24, 2003) (codified at 42 C.F.R. pt. 482) ("In this final rule, we are not setting a requirement for using and reporting on a core set of evidence-based performance measures. Once the evidence and methodologies to support a set of performance measures that can be used nationwide are available, we will assess issues such as commonality of data elements,

quired, other than through acknowledgment of JCAHO and its requirements of error reporting.[225]

CMS is a reluctant regulator, and the new error rule reflects the culture and history of CMS (previously HCFA, the Health Care Financing Administration). This CMS rule is quite modest in its ambitions, tracking the JCAHO standards closely, and sounding more aspirational than compulsory in its tone. The Rule mentions in a mildly threatening way the possibility that a hospital's Medicare status might be denied if a hospital does not implement proper error detection systems; the lack of explicit mandates for error reporting however remove teeth from the Rule.[226] CMS, like HFCA before it, has traditionally viewed itself as a funding agency, not a regulatory one, and this rule reflects that tradition of a timid regulatory stance and reliance on the parallel efforts of private accreditation. As Michael Astrue has described CMS and its historical roots, it is a reluctant regulator. "HCFA [now CMS] has attempted to minimize its role as regulator through liberal use of private contractors and private accrediting agencies."[227] So the rule may be a step in the right direction, but a small and timid one. Eighty years after Codman developed his model of a result-based outcome system for hospitals, both JCAHO and the federal government are finally beginning to move health care institutions in this direction. It has taken the image of almost 100,000 unnecessary deaths a year, painted by the IOM report, to move us to this point.[228]

C. The State as Leader: The Pennsylvania Patient Safety Authority

Pennsylvania passed a new law in 2002 to address patient safety and medical errors, as part of a larger legislative package to reform the malpractice system.[229] The centerpiece of this reform legislation is the Patient Safety Authority and accompanying require-

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standardization, and reporting systems. We will inform hospitals and the public of the specifics of and the methods for reporting these performance measures via future rulemaking. This will give the public the opportunity to comment on the core measures before implementation.").

[225] Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3436.

[226] Id.

[227] Astrue, supra note 200, at 77.

[228] See INSTITUTE OF MEDICINE, supra note 1.

[229] Medical Care Availability and Reduction of Error (Mcare) Act, PA. STAT. ANN. Tit 40 § 1303 (2002).

ments imposed on providers to reduce medical errors.[230] The law is Act 13, the Medical Care Availability and Reduction of Error Act, part of a larger legislative enactment with malpractice and insurance reform components.[231] It has several central features: mandatory reporting to the state of serious events, incidents, and infrastructure failures; mandatory disclosure of serious events to patients; and penalties for failures to report.[232] The Authority has eleven members, and is chaired by the Physician General of Pennsylvania. The member is comprised of four residents appointed by the legislature, and six appointed by the Governor, including a physician, a nurse, a pharmacist, a hospital health care worker; and two state residents.[233]

The statute defines "incident" as "[a]n event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.[234] The term does not include a serious event.[235] It also defines "infrastructure failure": "[a]n undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety."[236] A 'serious event' is "[a]n event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient."[237] The term does not include an incident."

Section 303 established the new Patient Safety Authority, comprised of eleven members: the Physician General of the Commonwealth; four residents appointed by the legislature; a physician; a nurse; a pharmacist; a health care worker in a hospital; and two residents of the Commonwealth, one of whom is a health care worker and one is not.[238] Among the powers of the Authority is to the

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[230] Id.

[231] Id. at § 1303.313.

[232] Id.

[233] Id.

[234] Id. at § 1303.302.

[235] Mcare, PA. STAT. ANN. Tit 40, § 1303.308.

[236] Id. at § 1303.302.

[237] Id.

[238] Id. at § 1303.303.

power to contract with a for-profit or registered nonprofit entity or entities, other than a health care provider, to do the following:

> (i) Collect, analyze and evaluate data regarding reports of serious events and incidents, including the identification of patterns in state facilities;
>
> (ii) Transmit to the authority recommendations for changes in health care practices and procedures, which may be instituted for the purpose of reducing the number and severity of serious events and incidents.
>
> (iii) Directly advise reporting medical facilities of immediate changes that can be instituted to reduce serious events and incidents.[239]

The Authority can issue recommendations to a medical facility as to improvements in health care practice and procedures to reduce the number and severity of serious events.[240] A whistleblower provision allows a health care worker to anonymously report a serious event, triggering an investigation unless the facility has already begun its own investigation.[241]

The statute requires the development of a patient safety plan, which must designate a patient safety officer; establishes a safety committee, and a system for workers to report "serious events and incidents which shall be accessible 24 hours a day, seven days a week"; prohibits retaliation against workers who report a serious event; and provides for written notification to patients under 308(b).[242] A serious event must, under 308, be reported to the state within twenty-four hours of its discovery.[243]

Providers are granted, under 311, protection from discovery of documents and materials prepared for compliance with 310(b) "which arise out of matters "reviewed by the patient safety committee pursuant to section 310(b) or the governing board of a medical facility pursuant to section 310(b).[244] Such materials "are confidential and shall not be discoverable or admissible as evidence in any civil or administrative action or proceeding. Any documents, materials, records or information that would otherwise be available from original sources shall not be construed as immune from discovery or use in any civil or administrative action or proceeding merely because they were presented to the patient safety committee or gov-

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[239] *Id.* at § 1303.304

[240] Mcare, PA. STAT. ANN. Tit 40, § 1303.304.

[241] *Id.* at § 1303.304.

[242] *Id.*

[243] *Id.* at § 1303.313.

[244] *Id.* at § 1303.311.

erning board of a medical facility."[245] This immunity provision is quite extensive and appears to be broader than the current statute for peer immunity generally in Pennsylvania.[246]

A medical facility must report a serious event to the department and the authority within twenty-four hours of the confirmation that such an event took place, under section 313.[247] Incidents must also be reported, under subsection (b), and subsection (c) mandates a report of the occurrence of an infrastructure failure report within twenty-four hours of the facility's confirmation of the occurrence or discovery of the failure.[248]

The penalties for failure to report are two fold. The individual physician or nurse may be reported to the state licensing board for a failure to report a serious event.[249] If the medical facility fails to report or notify, or to develop and comply with a patient safety plan, a double effect occurs. First, it is treated as a violation of the Health Care Facilities Act and its penalties attach; second, the new statute allows for an administrative penalty of $1000 per day to be imposed by the department.[250]

A patient must be notified if he or she has been affected by a serious event. The statute provides:

> 308(b) Duty to notify patient.—A medical facility through an appropriate designee shall provide written notification to a patient affected by a serious event or, with the consent of the patient, to an available family member or designee, within seven days of the occurrence or discovery of a serious event. If the patient is unable to give consent, the notification shall be given to an adult member of the immediate family. If an adult member of the immediate family cannot be identified or located, notification shall be given to the closest adult family member. For unemancipated patients who are under 18 years of age, the parent or guardian shall be notified in accordance with this subsection. The notification requirements of this subsection shall not be subject to the provisions of section 311(a). Notification under this subsection shall not constitute an acknowledgment or admission of liability.[251]

This provision, like JCAHO's patient notification provision, seems intended to promote candid disclosure of errors by facilities,

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[245] Mcare, PA. STAT. ANN. Tit 40, § 1303.311.

[246] Peer Review Protection Act, PA. STAT. ANN. Tit 63 § 425.3, (July 20, 1974).

[247] Mcare, PA. STAT. ANN. Tit 40, § 1303.313.

[248] *Id.*

[249] *Id.*

[250] *Id.*

[251] *Id.* at § 1303.308(b).

on the theory perhaps that such disclosure and an apology will reduce litigation.[252]

The new Pennsylvania Patient Safety Authority is unique. No other state has yet created such a regulatory body with a mandate to compel reported of series events and incidents ("near misses"), and to mandate disclosure to patients of serious events. The Authority sees itself as assuming a leadership rather than a regulatory role, hoping to build a hospital culture in favor of error reporting and analysis, without fear of retribution.[253] From a regulatory perspective however what is most interesting about the new Pennsylvania law is that error reporting is mandatory, that a hospital can be fined for underreporting and that whistleblower protection is provided to promote detection of underreporting.[254]

VI.   CONCLUSION

The three overlapping regulatory approaches to medical error disclosure illustrate three rather distinct regulatory strategies. The JCAHO sentinel events policy has responded to hospital anxiety by cloaking errors in secrecy, even though peer immunity statutes are likely to protect them from disclosure during civil discovery. Their level of reporting is still considered to be quite low. JCAHO continues its delicate tiptoeing around hospital concerns, as has been the tradition with such a private accrediting body. The CMS rule is too new to evaluate but it clearly is a "go-slow" policy allowing hospitals substantial time to develop reporting systems for errors. Such data collection is strongly urged but the mechanics of it are left up to hospitals during this cycle of the rule. CMS continues its role as reluctant regulator, only slowly moving toward recognition of the magnitude of the medical error problem.

Pennsylvania through its Mcare law now has the strongest regulatory approach to properly address error detection and reduction. The Pennsylvania law in other words has teeth in mandating reporting of errors. This concept of mandated reporting—backed by both state immunity from discovery of the reports and sanctions for failures to report—puts incentives in tandem. As the Patient Safety

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[252] Letters now in use by some hospitals to satisfy the statute are typically brief and very general, leaving the specific details to a discussion between the provider and the patient. What really happens, and the extent of disclosure and apology, is therefore concealed.

[253] Interview with Dr. Stanton Smullens, Member of the Pennsylvania Safety Authority, in Wilmington, DE. (Feb. 6, 2003) (on file with author).

[254] Mcare, PA. STAT. ANN. Tit 40 §1303.308.

Authority develops its staff and its reporting, it will bear close watching. It has the potential to become a model for other states, leaving JCAHO and CMS to catch up.