The Implementation of Quality and Safety Measures: From Rhetoric to Reality

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ABSTRACT: The evolution of American healthcare is the history of recurrent attempts to enhance quality of care. The latest wave of debate in this area was sparked by the 1999 Institute of Medicine Report, *To Err is Human*. In the current debate over how best to improve safety and quality, however, there has been a disconnect between the theoretical optimum and the practical possibilities. The author examines the history of our nation’s efforts at healthcare improvement over the years, and concludes that the present debate will likely lead to improvements—but only after a messy (and necessary) political struggle over what price Americans are willing to pay for improvement, and where that money will come from. When reform occurs, the author believes that it will be on multiple levels, with accreditation organizations and various levels of government acting in the manner (and for the constituencies) appropriate to each. Ultimately, the political processes will yield a variety of approaches to be watched, studied, and amended as the healthcare system evolves to provide safer, more effective care.

It is fashionable to attribute a renewed focus on quality of care and patient safety to the 1999 Institute of Medicine (IOM) Report, *To Err Is Human*. In fact, the evolution of quality assurance for healthcare institutions predates that report by almost 150 years. Healthcare quality in America traditionally has been the subject of periodic reform activity; the IOM Report merely provides a landmark date by which to measure the latest activity regarding healthcare quality and patient safety reform.

There remains, however, a vast difference between the ideals of those who propose improvements in quality and safety (the

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“rhetorical process”) and the political and budgetary realities facing those who would promulgate and enforce new quality assurance standards. The development of proposals to improve quality and safety standards and measures through the rhetorical process is only the beginning of the reform process. In order to actually create a safer, more effective health system, these proposals must be incorporated into state or federal regulations or accreditation standards. It is the process by which rhetoric becomes reality that creates the heuristics for systemic improvement.

The purpose of this article is to establish a common understanding of the definitions of quality and patient safety—the language of the rhetorical process; to differentiate the respective roles of the federal government, state governments, and accreditation organizations; and to evaluate recommendations to improve the healthcare system by virtue of their capacity for implementation and in the context of the interests of stakeholders in the system.

I. Quality and Patient Safety: The Terminology

Quality and safety are two distinct concepts that are often used together, yet mean different things with respect to healthcare. The distinction is important because patient safety is more amenable to improvement in the current regulatory and accreditation construct than is quality. According to the IOM, quality of care is the “[d]egree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” Patient safety, by contrast, is defined in the IOM Report in part as “freedom from accidental injury.” The definition also provides that “ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur.”

Stated succinctly, quality of care is about outcomes, while patient safety is about the structures and processes in healthcare facilities that prevent or reduce the risk of harm. These definitions track the current understanding of how healthcare is regulated. As Avedis Donabedian described over twenty years ago, any assessment of the quality of healthcare comes down to measurable aspects of structure, process, and outcomes. Virtually all healthcare regulations and accreditation standards are built on the concepts. Therefore, it is easier to place improvement propos-
als that can be described as structure, process, and outcomes constructs within an existing system.

Structure is the availability of resources, including human, physical, and financial resources, as well as the system design. While structure is critically important to the provision of quality care, structural surveys give very little current information about the quality of healthcare. Structure is virtually useless in evaluating the ongoing quality of care. For that purpose, an assessment of process and/or outcomes is necessary.

Process is a normative behavior, as derived from medical science or from societal ethics. It is what the actors in the system do. The advantages of using a process-based method of assessment are that procedures are well-documented, accessible, timely, and permit specific attribution of responsibility for successes or failures. One can tell whether a process is followed even when one cannot tell whether it does any good.

When the causal connection between certain procedures and outcomes is weak, normative validity, or general acceptance of the use of certain procedures in certain circumstances, may be the best way to evaluate quality of care. Examples of process measures include credentialing requirements, utilization review, and complaint and grievance systems. Many of the data collection efforts in managed care measure the success of process. For example, the percentage of members receiving beta-blockers or mammograms reveals information about the processes of a managed care organization without directly telling us anything about patient outcome.

Donabedian describes the term outcome as “a change in a patient’s current and future health status that can be attributed to antecedent health care.” Outcomes are, or should be, the best result of appropriate structure and effective processes. Using outcomes to assess quality promotes a more flexible and open approach to the provision of care. Physicians will be encouraged to use the most effective processes, which may have the effect of lowering costs without diminishing quality of care. Using an outcome-based method of assessment may also enhance patient input into quality assessment, because the patient will be a primary source of data. This, in turn, may encourage physicians to improve their relationships with their patients. Even so, outcomes are still very difficult to measure. Even when an optimal outcome can be determined, it is often difficult to
attribute responsibility for the outcome to either a specific procedure or the totality of the medical care.\textsuperscript{10} This may lead to the use of redundant procedures or other excessive or costly care.\textsuperscript{11} Finally, there is often a long delay between application of care and its outcome, making monitoring very difficult.\textsuperscript{12}

The Donabedian analysis is important in a discussion of patient safety and quality for two reasons: first, patient safety is linked to structure and process, while quality refers to outcomes and how they are achieved; second, those who regulate healthcare providers and payors, whether in state, federal, or nongovernmental settings, rely upon this construct. Virtually every healthcare facility or payor licensure regulation, participation requirement, or accreditation standard can be characterized as a structure, process, or outcome measure. This is how regulators, policymakers, and stakeholders think about healthcare. Stakeholders, legislators, and executive branch policymakers tend to support those proposals for which they have precedent and which can be implemented with a minimum of cost or alteration of existing methods of operation either by regulators or the regulated communities.

The tripartite analysis of structure, process, and outcomes has limitations. Defining outcomes and then collecting data to evaluate them is far more difficult than assuring that appropriate structures are in place and processes are used. For example, regulations mandate the space and equipment available in operating rooms, the composition of the surgical team, and the credentials of all involved (including the patient in some cases), but cannot assure a quality outcome. Systems are so complex that, even with these safety measures in place, the variables involved create a possibility that something will go wrong. Moreover, the collection of data does not in itself assure quality; it merely informs the collector about the status of patients who have certain diagnoses or treatments, in a particular timeframe. As discussed, the existence of structures and processes cannot assure quality outcomes, though they provide the most effective means, given human frailties, of achieving patient safety.

Despite these shortcomings, the Donabedian analysis is useful as a means for placing the results of the rhetorical process about patient safety and quality of care into a structure familiar to those involved in the policymaking process—that is, to those charged with improving the system by translating ideas into the reality of law.
II. The Distinct Roles of State and Federal Governments and Accreditation Agencies

Without belaboring the limits of the rhetorical process of developing patient safety and quality of care measures, once the important work of developing ideas for systemic improvement has been placed into a construct useful to policymakers, the next consideration is whether the appropriate venue for implementation is state or federal government or the accreditation organization(s).

A. Federal Powers

While seemingly elementary, any discussion of the distinction between federal and state law should begin with the Constitution of the United States. The Tenth Amendment explicitly states that “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”

The Constitution does not mention healthcare or healthcare regulation. From the time of the founding of the United States, the regulation of healthcare has been primarily a state function. Indeed, in the seminal case of *Gibbons v. Ogden*, Chief Justice Marshall stated that “health laws of every description” fall within the police power of the states. The Supreme Court consistently has held that the states may exercise their police powers to protect the health and safety of the citizens, reasoning that these “health and safety matters are primarily, and historically, a matter of local concern.” “The States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”

With respect to the exercise of state police power in and of itself, by the early twentieth century the Supreme Court “distinctly recognized the authority of a State to enact quarantine laws and ‘health laws of every description.’” The Court, in *Jacobson v. Massachusetts*, adhering to this well-settled principle, stated that “the police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.” The *Jacobson* Court also held that, when state laws regarding health “went beyond the necessity of the case, and, under the guise of exerting a police power, invaded the domain of Federal authority, and violated rights secured by the Constitution, this court deemed it to be its duty to hold such laws invalid.”
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Moreover, the Court held that judicial authority to review state health laws exists only when “a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law.”

Therefore, state health laws bearing a substantial relationship to public health goals could not violate the Constitution.

Until the enactment of Depression-era legislation, state police powers were considered inviolate with respect to public health. The federal government began to exert itself with respect to health-related issues during the 1930s, thereby preempting state health laws for the first time. As the federal government began to assert its authority, the roles of the states with the federal government evolved into the complex intertwined and interdependent system we have today.

B. The Origins of Quality Assurance by State Governments

State oversight of the practices of institutional healthcare providers derives from the governmental efforts to provide relief from disease, alcohol abuse, poverty, and crime in the early nineteenth century. These social ills were considered related and subject to a similar treatment—usually placement in institutions. These institutions were designed for charitable and correctional purposes; however, “the undifferentiated almshouse failed to classify and segregate from one another the sick, insane, the sexes and children.”

The gross failure of the almshouse system led to state supervision of charitable institutions, eventually including hospitals. Massachusetts established the first Board of State Charities in 1863, followed by New York in 1867. Pennsylvania established its Board of Public Charities in 1869. Illinois created its State Board of Health in 1877. These boards were empowered to examine the condition of all charitable, reformatory, or correctional institutions. Such institutions were considered separately. No longer was the care of the poor, infirm, and convicted considered the same. Later reforms continued the differentiation, which was exemplified by the establishment of the Pennsylvania Board of Public Charities, Committee on Lunacy in 1883. The 1883 reforms in Pennsylvania, which were similar to those in other states, permitted the board to recommend corrections to practices and to “compel obedience” at the institutions under the board’s supervision.
The creation of state entities with the authority to recommend changes and to compel obedience was the precursor to the establishment of state departments with the authority to license and sanction healthcare facilities. In 1917, the American College of Surgeons (ACS) established minimum standards for hospitals and introduced a voluntary system for compliance. The ACS standards succeeded the Flexner Report, which provided standards for modern medical education and preceded the development of modern public health departments at the state level, many of which were charged with the supervision of healthcare institutions. In 1923, Pennsylvania invested the recently-created Department of Welfare with the authority to correct “unlawful, unhygienic, or detrimental” institutional conditions. Likewise, in 1917, Connecticut created its State Department of Health, which began licensing hospitals and nursing homes in 1927. The New York Board of Social Welfare oversaw the regulation of hospitals from 1927 until 1965.

Pennsylvania granted its Department of Public Welfare the authority to supervise state health institutions. Supervision was considered to be the periodic monitoring of ongoing care, whereas licensure is the state imprimatur required prior to providing care. Indeed, the department’s ability to promulgate rules and regulations providing for licensing was limited to “houses or places in which any person can be lawfully detained as an insane person.” Furthermore, an examination of the language used in reports by the agencies and commissions that performed supervision in the late nineteenth and early twentieth centuries reveals that the department provided suggestions and counsel rather than sanctions to effect compliance.

In 1946, Congress passed the Hill-Burton Act to provide funds for states to build hospitals. Hill-Burton conditioned state receipt of building funds on the plans submitted by states that “provide minimum standards (to be fixed in the discretion of the State) for the maintenance and operation of facilities providing inpatient care.” While Congress later referenced a model law based upon ACS standards, states remained free to select methods of obtaining compliance. For example, in Pennsylvania, it was not until the late 1970s that the state’s authority to license healthcare facilities was recognized.

C. The Recognition of Nongovernmental Authority and the Rise of Accreditation

By the 1950s, the ACS and its standards were replaced by the Joint Commission on Accreditation of Hospitals (JCAH), now known
as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Original members of the JCAH included the ACS, the American College of Physicians, the Canadian Medical Association, the American Hospital Association, and the American Medical Association. JCAHO accreditation is now a benchmark for both state licensure and Medicare participation.

D. The Role of Physician Licensure

Concomitantly, the regulation of medical professionals developed from a guild-like licensure system controlled by medical societies in the eighteenth century to the peer review physician licensure systems controlled by public licensure boards of the late nineteenth century.

Originally, many eighteenth-century statutes delegated licensure responsibilities to medical societies, which acted as the guild of the medical profession. However, as Professor Jost has described, “[a]s the nineteenth century progressed . . . occupational licensure was largely abandoned, and by 1850 the medical profession had been almost totally deregulated.” Licensing was reborn in 1873, when Texas enacted a physician licensure statute; in the course of the next thirty years, every other state followed.

Physician licensure statutes mandated graduation from recognized schools, specified training periods, and passage of an examination prior to practicing the profession. The intent of these requirements was to ensure that the physician had the ability to practice medicine with some level of competence. “Licensure was concerned with the capacity to deliver minimally adequate care, not with the actual delivery of optimal care.”

An important aspect of the late-nineteenth-century physician licensure movement was that it was based upon peer review, though not directly under the control of guild-like medical societies. In contrast to their eighteenth-century forerunners, which delegated licensure responsibilities to medical societies, late-nineteenth-century statutes established public licensure boards—the members of which were chosen by state government. Medical societies, however, “continued to dominate the appointment process, and as recently as the late 1960’s [sic] statutes in a third of the states required that medical board members be appointed from persons nominated by medical societies.” Indeed, many states still use medical societies to obtain nominees to medical boards, even if the law no longer requires them to do so.
Many state medical licensure boards now seek to address quality by including nonmedical members, mandating continuing medical education, and disseminating practice information or “report cards.” Nevertheless, the focus of medical boards remains on enforcing minimum qualifications to enter the profession and policing the behavior of licensees. Licensure boards continue to concentrate on misbehavior (mostly sex, drugs, or alcohol-related), rather than on malpractice or other pending issues.

E. The Integration of Accreditation and Licensure

Licensure has been described as the vehicle for states to assure that minimum standards are met before a healthcare provider or facility provides care. State imprimatur is necessary, because no other entity exists elsewhere to protect the citizens before they receive care. Therefore, a licensure regimen, along with the personnel dedicated to the task of oversight of healthcare facilities, is necessary for ongoing assurance of minimum quality and patient safety. Combining the constitutional concepts with the Donabedian analysis, as a matter of public safety it is uniquely a state responsibility, and it is within state power to set and enforce standards for patient safety and quality. The role of licensure is to ascertain that the facility’s infrastructure, both structural and personnel, as well as its method of providing care, and in Donabedian terms its processes, will not endanger patients, but will create an environment conducive to the provision of care.

The federal government performs virtually no direct healthcare oversight. Rather, it relies on two methods of external review to ensure hospital compliance with conditions of participation in Medicare: (1) accreditation by the JCAHO or other private accreditation organizations; and (2) Medicare certification by state healthcare licensing organizations.

Indeed, the entire system of Medicare certification, including the certification standards, is built upon these collaborative arrangements. The conditions of participation are developed in consultation with states and accreditation agencies. The Secretary of Health and Human Services will consult with state and recognized accreditation agencies to determine compliance with standards for participation in the Medicare program. State licensure is a statutory condition of participation for hospitals, while accreditation is a voluntary means of meeting the conditions for participation.

As the Medicare-certifying agencies, states assume the direct responsibility for oversight on behalf of the federal govern-
This responsibility includes conducting surveys and assessments of nonaccredited facilities to ascertain their compliance with Medicare conditions of participation. Indeed, the state Medicare certification function is a natural adjunct to ongoing state activities such as licensing and the setting of standards.

While the Medicare program permits accreditation to substitute for state certification, federal standards and accreditation standards, and the manner in which states and accreditation agencies work, are very different.

State oversight through licensure, certification, and complaint and incident investigation is the foundation of the public quality assurance and patient safety accountability system. Without the state role, neither accreditation nor certification would have any value, because the baseline indices of patient safety and quality would not exist. Accreditation serves different purposes from licensure and state-conducted Medicare certification. Indeed, JCAHO summarizes the differences between accreditation and licensure/Medicare certification surveys on its Web site. According to the JCAHO, the purpose of accreditation surveys is to improve performance and obtain deemed licensure status in some states. By contrast, the purpose of state surveys is “licensure and/or Medicare/Medicaid provider certification.” However, this is only facially correct. The purpose of a state survey is to ensure a base level of safety and quality assurance in a surveyed facility. Licensure and/or Medicare certification are merely the outcome following the survey results.

JCAHO describes the emphasis of its accreditation surveys as “evaluation,” in contrast to the emphasis state surveys place on “inspection.” The emphasis of state surveys, however, is not merely on completing inspections for the sake of the task, but rather to serve the previously-described purpose.

States approach surveys with the intent to compare a facility's performance with minimum expectations contained in the law and the goal of achieving such mandatory compliance. JCAHO and other accreditation agencies survey to compare a facility’s performance with aspirational standards with the goal of improvement. States sanction facilities that fail to meet regulatory requirements, while accreditation agencies educate and consult with facilities that fail to meet standards.

Accreditation standards and regulatory requirements are entirely distinct, yet the development of each involves a cross-fertiliza-
tion of ideas. Licensing regulations are often based in part on accreditation standards. Likewise, accreditation standards are often an extension of licensing regulations. However, neither is replicable by the other. Accreditation only works if it is built on a licensure platform, and licensure is most effective in promoting quality improvement if facilities also seek accreditation.

III. Proposals for Improvement in Quality Assurance and Patient Safety

The latest stage in the evolution of patient safety and quality of care has been marked by an abundance of proposals. Patient safety and quality of care have become rhetorical political priorities, matters to be discussed endlessly but almost never acted upon. Indeed, the post-IOM Report era has yielded innumerable proposals for reform, few of which focus on the essential matter of implementation. Rather than analyze the vast trove of proposals, this article will discuss a few common proposals from the perspective of who will implement them and how they might become part of the patient care safety net.

The Agency for Healthcare Research and Quality (AHQR), through the University of California at San Francisco-Stanford University Evidence-based Practice Center (EPC), reviewed the scientific literature regarding safety improvement. The purpose of this exercise was to critically appraise the evidence on which patient safety practices were best supported. The AHQR-EPC study provides an excellent starting point for a discussion of patient safety proposals.

In addition to the critical appraisal of proposals, the AHQR-EPC study is also useful because it recommends a distinction between those proposals that are best implemented by those who provide care and those proposals that may effectively be required by state regulation, Medicare participation requirements, or accreditation standards.

The vast majority of patient safety proposals involve changing the standards of care that inform the practice of medicine or the provision of healthcare in an institutional environment. They do not directly involve the imposition of regulatory requirements, accreditation standards, or conditions of participation. That is not to say that there is no role for external oversight. Indeed, Chapter 55 of the report, entitled Legislation, Accreditation and Market-Driven and other Approaches to Improving Patient Safety, briefly discusses the regulatory and other governmental means
for implementing patient safety regulations. While this is a useful chapter, it fails to comprehend the actual work of regulators and accrediting agencies. Another heuristic for determining the appropriate role for government oversight would be more useful—specifically, a return to the Donabedian analysis.

Recall that government regulators, in this case usually state regulators, enforce standards related to the structure, process, and outcomes of the provision of healthcare. Many of the proposals for improving patient safety do not fall within either of the three categories. There are, however, proxy measures that serve to accomplish the same goal. For example, Part III, Section B of the AHQR-EPC study concerns infection control measures. It would not be appropriate for regulations or accreditation standards to mandate specific types of infection control measures. Regulations and standards do not change quickly enough to keep pace with advances in science and medicine. By contrast, requiring facilities to have infection control officers or committees is a structural measure; requiring facilities to have a process for tracking and treating infections and for reviewing the number, type, and location of infections would be a process measure; and mandating the collection and reporting to state authorities, or to independent bodies, of the number and type of infections and the success in treating them is also a process measure. All of these measures fall within the nature of healthcare regulations without mandating the type of science or medicine to be applied.

Likewise, virtually any type of data collection and analysis is a function for which government is both statutorily and functionally well-suited. Government can mandate data collection and submission. It can mandate the collection and internal analysis of data collected by facilities. Equally, state governments can limit discoverability, admissibility, and liability for the information contained in the data collected. States also can mandate the format used and the use of identifiers, thereby dramatically impacting both the cost and utility of the data collection and analysis process. Healthcare providers generally dislike data collection and submission because it is a time-consuming, expensive, and unproductive exercise with no discernable direct benefit. The challenge for governments 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.
IV. Improving the System and the Political Process

Attaining patient safety and quality improvement in the healthcare system is dependent upon the translation of the important products of the rhetorical process into policy. That policy can be in the form of accreditation standards, federal statutes, regulations, or participation requirements, or state statutes or regulations. Despite the efforts of the Leapfrog Group and other business constituencies, it is difficult for the market to force systemwide improvement. That is not to say that large purchasers might not be able to negotiate for patient safety and quality of care measures, but those measures come at a cost that the purchaser must be willing to bear. As health coverage costs continue to increase, devotion to patient safety and quality assurance must be justified to purchasers as a means of showing long-term savings. By contrast, the political process accounts for cost differently—as an issue to be considered, but not necessarily dispositively.

In the absence of a political constituency for quality assurance and patient safety, and given the weakness of market forces, the debate regarding how to change the system to benefit the public at large is left to the elected officials who seek change and to the stakeholders who have an interest in the potential benefits and costs of such change. As the patient safety and quality assurance components of the healthcare system evolve, several different types of stakeholders emerge. The traditional participants in the think-tanks and other forums that serve as the intellectual backdrop for these debates (such as academics, organizations devoted to quality assurance, consumer representatives, proponents of one kind of change or another, and government officials who perform data collection and analysis) give way to more traditional political stakeholders. The participants in the law and policymaking discussions generally include representatives of the health insurance industry, professional liability insurance industry, the trial bar, elected representatives and their staffs, and the representatives of providers and facilities who participate in a broad range of policy discussions.

The development of patient safety and quality assurance law and policy provides a paradigmatic view of the transition from rhetoric to law. It is easy for aggregations of interested persons, including government agencies, to develop model policies in isolation. To their credit, the authors of the AHQR-EPC study attempted to account for the strengths and weaknesses of various
proposals and the public and private regulators who might implement them. They were not so bold (nor was it their charge or in their political interest to be so bold) as to address the underlying political realities of implementing patient safety and quality of care proposals.

In reality, the policies must be implemented as part of the larger web of laws, standards, and policies that apply to healthcare providers. The political process is the mechanism through which the model policies developed in isolation are subjected to reality. It may be that the concerns raised by the stakeholders, who participate in the law or policymaking process, do not reflect what would be considered the greatest “public good” from an objective perspective. Nonetheless, one might suggest that, in a representative democracy, there is no objective public good. Public policy is made in the forum of competing interests. A short description of the interests at play in the patient safety and quality of care debate follows.

The development of law and public policy regarding patient safety comes at a cost, and is inseparable from decisions regarding how such law and policy will be financed. Therefore, it is not only necessary but appropriate that these discussions be linked to discussions regarding reimbursement, distribution of tobacco settlement dollars, the cost of professional liability insurance, the impact on health insurance and managed care costs, and so on.

The health insurance industry cares about the issue of patient safety from two perspectives. First, it wants to avoid additional regulation of its products. Second, to the extent that systemic improvements are imposed on healthcare providers, those costs will be reflected in the negotiation of reimbursement between healthcare insurers and providers. From an insurer’s perspective, such costs are indirect mandated benefits. Increasing costs to the insurer is reflected in the cost of coverage to individuals and employers. Such increasing costs will generally raise opposition from the business community.

The trial bar, representing plaintiff’s lawyers, participates because, given its political leverage, it can. It also has significant concerns in the public policy debate. First, the current crisis in the cost and availability of medical malpractice insurance has raised the specter of limitations on damage awards in order to preserve or restore the fiscal integrity of healthcare providers. Naturally, the trial bar opposes any such changes. Second, to the extent that data collection is protected from discovery, the activity could
limit the type of information available to trial lawyers trying to make a case. Third, if changes in the patient safety and quality assurance laws include strengthening professional boards and improving their ability to collect data, the odious practice of subjecting malpractice settlements to confidentiality agreements is threatened. The trial bar tries to couch its arguments in terms of protecting injured patients, but it vociferously opposes systems that, outside the judicial system, would ensure that injured patients receive compensation. This opposition leads one to believe that the trial bar’s greatest interest is in the preservation of contingency fee levels.

For their part, healthcare providers have the greatest vested interest in improving patient safety and quality of care. The IOM Report and highly-publicized incidents of compromised patient safety or poor quality care have harmed the reputation of the entire industry. Yet the cost of implementing patient safety and quality-of-care initiatives may not justify the benefits absent some compelling legal reason to engage in the activity. For example, Computerized Physician Order Entry (CPOE), one of the three major proposals from the Leapfrog Group, is so expensive that implementation would require significant diversion of resources from other healthcare priorities in the hospitals that use it. Moreover, if hospitals or other facilities are required to add layers of oversight or to perform functions in a new way, such as adding a patient safety officer, an infection officer, or safety committee, then they must divert human resources from remunerative activity into important but noncompensable activity. In an era of declining or stabilizing reimbursement, adding costs without revenue may detract from a facility’s ability to fulfill its core mission of actually providing care. On the other hand, if the mandated changes are subsequently reflected in negotiated rates with payors, then their cost becomes an indirect, mandated insurance benefit.

The doctors, for their part, have focused upon the so-called “NASA” model. The NASA model involves the use of both voluntary self-reporting of mistakes made in the course of providing care and confidential reports made to a nonregulatory body that will use the information to provide general advice on safety issues. The name comes from the current system for self-reporting by airline pilots who are required to self-report mistakes that they make to NASA, so long as no accident occurs. While the distinctions between flying an airplane and treating patients are too numerous to recount here, of greatest importance is that doctors are treating patients who have a right to know what
occurs in the course of their care. Even if a mistake does not appear to cause harm, the harm may not appear until later. By contrast, most airline passengers will not care if the pilot flies the plane at the wrong altitude unless the mistake causes a problem, in which case the voluntary reporting system is negated. Finally, physicians have had the privilege of peer review and licensure for 150 years, yet they remain lousy at identifying and weeding out their own bad performers. The state boards of medicine have an extraordinary opportunity to lead the effort toward improving patient safety and quality of care. In the regulatory realm, these boards work fairly autonomously. Were physician boards to mandate the use of certain patient practices as the appropriate level of care (through the use of accepted clinical practice guidelines, evidence-based medicine, or though working with nursing boards and other limited license professionals), they could profoundly improve the system. The challenge for such boards if they want such a role is to shed the notion of protecting the guild and accepting the responsibility of improving patient care.

V. Conclusion

Given the cyclical nature of the healthcare quality and patient safety evolution, the changes in healthcare quality and patient safety standards developed in this era of reaction to the IOM Report will likely provide the standards governing healthcare providers for the next twenty to thirty years. The nature of the parties interested in quality of care and patient safety make the development of this area of the law more difficult and complex then ever.

The fact that patient safety and quality of care become entangled in malpractice, reimbursement, and other issues merely reflects the complexity of the healthcare system and the political reality of joining similar issues—some with political weight, some without—in order to create laws to benefit us all.

Patient safety and quality issues need to be vetted in political debate to determine their importance in the constellation of important health issues facing our society. Meaningful system reform must include both the rhetorical process and the translation of the results of that process into meaningful regulations and reform. This reform can and will occur at a number of levels. Accreditation standards will reflect the measures that facilities and plans are willing to impose on themselves. Federal law will reflect those standards that transcend local and state interests. State law will reflect the interests of the stakeholders closest to the needs of providers, insurers, and patients. Ultimately, the states’
politiccal processes will yield a variety of approaches to be watched, studied, and amended as the healthcare system evolves to provide safer, more effective care.

Endnotes

1 INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000) [hereinafter IOM].
2 Id. at 211. The definition contains an internal contradiction by asserting that health services which would be considered quality healthcare services for individuals and populations are the same thing. They are not. The distinction is an important one. The healthcare industry has moved toward the use of critical pathways and disease management. However, those tools are based on the analysis of the healthcare needs of populations, not individuals. While these protocols may contain useful guidance in the treatment of individuals, they are not based upon analysis of individual patients and blindly applying these protocols to individuals is problematic.
3 Id.
4 Id.
5 1 Avedis Donabedian, EXPLORATIONS IN QUALITY ASSESSMENT AND MONITORING: THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT 83 (John Griffith et al., eds., Health Administration Press 1980).
6 Id. at 81.
7 Id. at 80.
8 Id. at 109.
9 Id. at 82-83.
10 Donabedian, supra note 5, at 120.
11 Id.
12 Id.
13 U.S. CONST. amend. X.
14 GIBBONs v. OgdEn, 22 U.S. 1 (1824).
15 Id. at 203.
18 For an extensive historical view of public health, see LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT (2000).
20 Id. at 25.
21 Id. at 28.
22 Id. at 31.
24 Id. at 196.
25 Id. at 197.
26 Id. at 198.
28 Shay, supra note 23, at 197.
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32 "The Flexner Report, written by Abraham Flexner for the Carnegie Foundation for the Advancement of Teaching and published in 1910, documented the serious problems in medical education at the beginning of the 20th century and helped set the course for its reform." Timothy Stoltzfus Jost, Oversight of the Quality of Medical Care: Regulation, Management or the Market?, 37 Ariz. L. Rev. 825, 868 n.31 (1995).
34 The Connecticut Department of Public Health, DPH History, available at www.dph.state.ct.us/DPH_Main/about_dph/history/history.htm (last visited Apr. 6, 2002).
35 Telephone Interview with Glen LaFave, Legislative Counsel, N.Y. Dept. of Health, Office of Governmental Affairs (Jan. 30, 2002).
36 1923 Pa. Laws 600.
37 1923 Pa. Laws 603.
39 Id. § 291d (a)(7).
42 Id. In 1959, the Canadian Medical Association withdrew from the JCAH. Twenty years later, in 1979, the American Dental Association joined.
44 See Jost, supra note 32, at 827-29.
45 Id. at 827-28.
46 Id. at 828.
47 Id.
48 Id.
49 See Jost, supra note 32, at 828.
50 Id. at 829.
51 Id.
52 Id.
53 Id.
54 See Jost, supra note 32, at 833-34, 837, 866.
55 Id. at 866-67.
56 Id. at 829.
57 See supra notes 5-12 and accompanying text.
61 See DHHS Review, supra note 58, at 6.
62 Id.
64 Id.
65 Id.
The plaintiff’s bar often claims a central role in the development of quality standards. Because the purpose of the tort system is to compensate an individual injured person, not to develop comprehensive or even rational quality assurance measures for a population, many of the quality assurance proposals are not the type of changes that would be best enforced by statute, regulation, or accreditation standards. Recall that, under the Donabedian approach, unless a standard is an identifiable structure, process, or outcome measure, it does not lend itself to enforcement. Rather, if such changes prove to be scientifically appropriate, then the medical community should remain responsible for incorporating such improvements into generally-accepted standards of care. Failure to provide a patient with care at such standards should expose the provider to tort system liability.

Having said that, the importance of the plaintiff’s bar is not in the development of case law concerning quality or in the size of the judgments or settlements, but rather in the role that it plays in the policy development process. The overstatement of the role in quality assurance is useful, in that it points out the shortcomings of the physician peer review system and provides a public policy justification for inclusion of plaintiff bar interests in the policymaking discussion.

The practice is odious because it prevents those charged with regulating healthcare providers from obtaining the very information necessary to regulate them. The practice shields the worst practitioners from the judgment of their peers and subjects other unwitting patients to the ill practices of such physicians.

To get some sense of the magnitude of cost, the State of California permits hospitals to choose between earthquake hardening and implementing CPOE, leading patients and payors creating networks to choose between those institutions in which a patient might be crushed under the weight of the building and one in which the medication system is not as safe as it could be.
