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A revisionist model of hospital licensure

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Abstract

This article explores the use of a new governance approach in the context of American acute care hospital regulation, specifically focusing on the core regulatory process of licensure. This article calls for the alteration of current command and control regulations through the adoption of a four-part revisionist licensing model. The model seeks to reinvigorate the licensing process by making it not only more relevant to efficient operations, but also adaptable to current industry challenges. Based generally on alternative regulatory models such as responsive regulation, meta-regulation, and management-based regulation, the revisionist licensing proposal is driven by the broad goals of bureaucratic reduction, participatory regulation, and more focused obligations. Elements of the model include refocusing on baseline requirements, problem identification and correction, negotiated obligations, and alteration of the structure of oversight. Specific application examples are provided in the areas of charity care and health planning.

Keywords: alternative regulation, bureaucratic reduction, hospital, licensure, new governance, participatory regulation, revisionist licensing model.

Introduction

There is a growing awareness in American health policy circles that the expansive regulatory oversights at federal and state levels are failing both the public and the health care industry alike. Beyond expected criticisms concerning the substance of particular government initiatives, a broader consensus is emerging that new forms of regulation balancing public health with the viability of provider institutions need to be found. While much of the criticism about regulatory inefficiencies in health care are directed toward the dominant use of command and control mandates, other forms of regulation in this sector, such as inspection/reporting and delegated regulation, are also seen as inadequate (AHA 2002). As such, consideration of alternative mechanisms of regulation, drawn from other industries and jurisdictions, is ripe for exploration in the American context. The large regulatory reform movement, often collectively referred to as new governance, has moved into the health care arena. It offers alternative oversight structures, typically in response to the stranglehold of administrative law processes.

This article draws on the work of health policy scholars in devising a new strategy for acute care hospital regulation, and borrows loosely from alternative regulatory strategies such as responsive regulation, meta-regulation, and management-based regulation.

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Specifically, this article explores a core area of American health care government oversight – the licensure of hospitals – and posits a four-part model for the established command and control process. While licensure may not offer a playing field for dramatic system reform, it is a well established modality that provides a workable platform for structural and content revisions in health regulation. Part 1 of the article presents a background discussion on hospital licensure, detailing past and current realities. Part 2 introduces a four-part model for hospital licensure, which entails (i) a reexamination of baseline requirements; (ii) a problem identification and response plan; (iii) the creation of institution specific obligations, with application examples being provided in charity care and health planning; and (iv) a revised regulatory structure, with the federal authority Centers for Medicare and Medicaid Services (CMS) acting as a meta-regulator. Part 3 explores barriers to the adoption of a revisionist model, and is followed by the conclusion.

1. Background on hospital licensure

General hospital licensure is a regulatory process that represents the convergence of several forces beyond the impulse of state regulators to protect public health (Capron & Birnbaum 2007). Unlike many core areas of state health care regulation, it was not until the 1950s that hospital licensing statutes were enacted around the country (Capron & Birnbaum 2007).¹ The original impetus to create uniform standards for hospital operations did not come from government, but rather was driven by organized medicine, namely the American College of Surgeons and the Council on Medical Education and Hospitals of the American Medical Association (later the Accreditation Council for Graduate Medical Education) (Capron & Birnbaum 2007). Hospitals, whether they are public, private, or charitable entities, have always faced certain corporate law requirements, as well as a need to comply with various zoning laws. Furthermore, in the case of specialized facilities, such as those treating patients with tuberculosis, the law sometimes requires the acquisition of municipal licenses (Hayt & Hayt 1940). The fact that many hospitals fit into the category of charitable institutions created a buffer from state licensure or certification, and exempted them from the scrutiny of state legislatures (Hayt & Hayt 1940). The American College of Surgeons, concerned over matters of safety and disparity in operations, launched a hospital standardization program to fill the regulatory void, and established minimum standards for accredited hospitals in the early twentieth century. The American Hospital Association (AHA) eventually took over the program and it later folded into The Joint Commission (TJC) (formally known as the Joint Commission on Accreditation of Health Organizations) (Capron & Birnbaum 2007). Under the auspices of the AHA, a model hospital licensing law was developed in 1945, which contained many of the elements state laws would eventually capture (Whitehall 1953).² The American Medical Association was also engaged in institutional standard setting through the creation of a Hospital Register. This was a voluntary system that required facilities to comply with a basic set of requirements in seven areas in order to qualify for listing as an institution that could sponsor medical internships and residency training.³

Legislatures initially enacted actual hospital licensing laws to regulate a narrow band of institutions, namely maternity hospitals, as well as private proprietary institutions. However, many states, prior to passage of hospital licensure laws, had requirements mandating inspection of hospitals, as well as some form of prescribed record keeping

(Capron & Birnbaum 2007).⁴ By the early 1950s, spurred by the prospects of federal grant and contract funding for hospital remodeling and construction under the Federal Hospital Survey and Construction Act (Hill Burton), as well as other federal funding programs that required compliance with minimum standards of maintenance and operations, most states enacted hospital licensing statutes or established specific operational requirements (Capron & Birnbaum 2007). As noted, the AHA created the template for modern hospital licensing laws, which served as the basis for this type of legislation around the country (Capron & Birnbaum 2007).⁵ Undoubtedly, state hospital licensing laws reflect the idiosyncrasies of jurisdiction. Certain states, such as New York and Michigan, have been highlighted for developing more detailed hospital licensing requirements that incorporated concepts of cost containment and facility planning, far earlier than other states (Capron & Birnbaum 2007). However, despite their variations, state hospital licensing laws are characterized by marked similarities, as similar pressures and incentives mold them.⁶ In fact, examination of general hospital licensing statutes and their accompanying regulations demonstrate that such laws were designed to, and continue to, function largely as a set of minimum entry and core operation standards. The hospital regulatory floor adjusts as necessary, and often serves as a platform for legislation and regulation to address current problems in the sector.⁷

What is particularly interesting about hospital licensure laws is that they, in fact, do not stand alone as a single regulatory structure, but must be viewed alongside two other sets of mandates (see Fig. 1). With the passage of Medicare in 1965, the federal government created an independent hospital regulatory mechanism, the Conditions of Participation (COP), which established a detailed set of requirements that hospitals must meet in order to participate in the Medicare/Medicaid program.⁸ In essence, the COPs are very similar to a licensing statute. However, due to a perception that state laws were too weak to protect public health and safety, Congress developed these new regulations (Capron & Birnbaum 2007). In addition to the Medicare COPs, hospitals have also been subjected to private regulation under the auspices of TJC. TJC is an entity created in 1951, sponsored by several large medical organizations in order to carry on the prior work of the American College of Surgeons, and later the AHA, in evaluation of acute care entities. Distinguished from its private sector predecessors, TJC developed a more detailed set of standards for hospitals, expanding their mandates into matters concerning administration, governance, physical plant, and services. By 1966, TJC accredited 76% of American hospitals, constituting 94% of all inpatients beds (Roberts *et al.* 1987).

On its face, it would appear that the framework of hospital regulation resting on the three platforms noted would spawn unnecessary duplication, and result in excessive compliance challenges. By and large, however, in the hospital licensing area, regulations and institutions have adopted a command and control system that is characterized by selective enforcement, and while long-standing, frequently lacks either a comprehensive or a coordinated vision. Interestingly enough, the three respective systems of regulation, state licensure, and MCP and TJC accreditation, over time have achieved a certain level of equilibrium, and in fact, the three processes largely operate in an interrelated manner. While authorities in a given state must license all hospitals, they may avoid separate certification by Medicare if TJC or the American Osteopathic Hospital Association (AOA), which act under authority delegated by the federal government referred to as "deemed status," accredit them.⁹ State licensing authorities, acting under contract on behalf of CMS, survey hospitals that are not privately accredited.¹⁰

The practical reality of how hospital mandates are applied may vary across the states, but from an operational standpoint, this area is more accurately classified as a dual system, split between public regulation and private accreditation. State licensing agencies' involvement with hospitals is most extensive at the point of initial verification of licensure standards. Beyond that process, the engagement of these regulators into hospital compliance matters, in some jurisdictions, is largely driven by a complaint-based system that exists under both state and federal law, as well as a process of random review (Unanue E 2006, unpublished interview).¹¹ Serious complaints can lead to a full state survey of an acute care facility, possibly multiple times in a given year. In certain states, authorities utilize separate state surveys that seek to provide alternative measurements of institutional behavior to those used by either CMS or TJC. In addition, states conduct investigations into certain CMS standards on a random basis, and validate a small number of TJC accredited facilities as meeting federal hospital guidelines (Unanue E 2006, unpublished interview).¹²

The state licensing authorities have broad responsibilities for initial and continued verification of a wide range of facilities and programs beyond hospitals, and are often confronted with serious financial challenges in meeting growing and complex review responsibilities, particularly in long-term care. The fact is that both the federal COPs and state licensing standards have been expanded considerably over time. The reforms are in response to a myriad of problems, sparked by changes in the nature and complexity of acute care, such as serious workforce shortages and employee turnover. Furthermore, hospital mandates have expanded in response to larger health policy concerns such as patient right issues, medical errors, and community benefit mandates (Capron & Birnbaum 2007).¹³ While both state licensing laws and Medicare's COP remain core, entry level regulations, the size of the regulatory floor has grown to a point where it taxes the abilities of authorities to monitor it. In addition, neither state licensing standards nor Medicare certification allow regulators the opportunity to engage in collaborative problem solving with the regulated entities, but instead tend to be highly prescriptive processes that identify deficiencies and mandate correction (Roberts *et al.* 1987).

Private regulation under the auspices of TJC does offer an alternative to government regulation of hospitals, and has become an established feature of the regulatory landscape. As noted, the process of "deemed status" has empowered TJC to act as the gatekeeper for hospital entry into the Medicare program. The history of this form of private accreditation is rife with controversy, as TJC accreditation is both voluntary and costly. If TJC pursues its tasks with too much vigor, it may result in institutions dropping the process, opting for other alternatives. On the other hand, TJC standards and surveys must provide the public, and government, with the sense that such monitoring is not pro forma, but is both meaningful and rigorous. For many years TJC has been locked into a cycle of "criticism – then – action" which has resulted in numerous new efforts in areas of quality and patient safety (Burda 2002). Perhaps the biggest catalyst for change in TJC accreditation, beyond a continual fear of losing membership, has been the national crisis in medical errors starting in the late 1990s that generally has called into question the viability and effectiveness of all hospital monitoring processes.¹⁴ Starting in 2004, TJC launched a new hospital accreditation program, referred to as "Shared Visions – New Pathways." This entails unannounced surveys, a focus on continuous self-assessment, and the application of a patient tracer evaluation that involves tracking a patient throughout the individual's entire hospital stay, including across departmental lines

(Katzfey 2004). Unlike government survey processes, in recent years, TJC has assumed a somewhat flexible approach and has designed standards that allow facilities greater leeway in meeting accreditation standards.

Undoubtedly, the winds of politics and the pressure to be more sensitive to hospital concerns have pushed TJC into a responsive regulatory mode, and could yield an even more collaborative approach to institutional oversight (Catalano & Oglesby 2006). Nevertheless, TJC will always reside between two masters, the health care industry and government; thus, it will continue to be a convenient foil for failures in the acute care system, many of which are beyond their control. Highly public failings of TJC have also created a favorable climate for consideration of alternative, private regulatory processes, most notably the adoption of broad based, multi-industry ISO 9001 standards, a global system widely used for quality control.¹⁵ Arguments will persist that there is room for private regulation of some sort in the hospital sector. Still, ultimate oversight of licensed hospitals rests with government. However, the track record of accreditation, based on delegation of authority to TJC and AOA, is not strong enough for it to act indefinitely as a foundational element in the regulation of acute care facilities.

2. A new regulatory model for general hospital licensure

Outside of the world of regulators who are directly involved in licensure activities and the hospitals themselves, awareness and assessment of licensing measures are rare. Even rarer are in-depth considerations of how licensure can be reworked to meet immediate and long-term needs in our health care sector. To many in health policy, hospital licensing represents the status quo, rooted in a continuing need for accountability, and only on occasion are these laws the subjects of broad public examination. While licensing may not be seen as the fodder of big ideas, as an established regulatory mechanism, it can serve as a basis for development and implementation of health reforms. Examination of hospital licensure over time demonstrates that in some manner, virtually all changes in hospital oversight must be integrated into this process. For the purposes of this article, hospital licensing becomes a compelling arena for regulatory change for three primary reasons. First, although certain aspects of the hospital licensing processes, particularly accreditation, may be contentious, it seems unlikely that the hospital lobby would argue against the need for government oversight in controlling entry, and for having a continued presence in institutional acute care. Even the most zealous market advocate is unlikely to champion a case for abolishing hospital licensure in favor of reliance on economic forces as the vehicle to guarantee that necessary standards for public health and safety are met. Second, as an established regulatory mechanism, licensing has an accompanying regulatory infrastructure, with a cadre of knowledgeable bureaucrats, and a detailed operational structure that supports it. Third, though hospital licensing remains first and foremost a vehicle to establish a regulatory baseline, legislators and bureaucrats have been willing to adjust to current needs by altering hospital mandates. In light of deep seated frustrations with health care, regulators may be ripe for incorporating new approaches into existing processes such as licensure. Undoubtedly, altering licensing requirements is not the magic bullet that will result in broad reforms of American health care. Nonetheless, changes of any sort in oversight of the delivery system are difficult to achieve and pursuing smaller strategies, which build on existing structures, may be more feasible than adoption of new theories and creation of entirely new regulatory formats.

2.1. Revisionist model

Legislators should view licensure as a springboard for deliberate, broad based reforms, and not merely as an area for conveniently layering on mandates in response to current pressures in the delivery system. Furthermore, it is easier for legislators to fashion creative changes here than in more visible areas of health regulation. They can interject new regulatory approaches into a hospital licensing reform proposal, perhaps not in a pure sense by replicating a particular new governance model, but rather through application of concepts that appear in respective new regulatory designs. In the case of the proposed revisionist model, the work of Braithwaite *et al.* (2005) in areas of responsive regulation and meta-regulation, and Coglianese and Lazer (2003) in management-based regulation, are directly relevant. In a broader sense, however, what is presented herein, while a milder adjustment to command and control regulation than is seen in alternative regulatory literature, is influenced greatly by reform goals of bureaucratic reduction, participatory regulation, and creation of more focused obligations (Braithwaite *et al.* 2005).¹⁶

The revisionist model of hospital licensing called for herein contains four primary elements: (i) refocusing on baseline requirements; (ii) problem-based identification and correction; (iii) the development of negotiated, institution specific regulatory obligations; and (iv) alteration of the current structural components of hospital oversight. To those to whom nomenclature matters, this model, in reference to identifiable new governance approaches, can be seen loosely as a hybrid spawned by work done in the area of responsive regulation, and to a lesser extent, management-based regulation. While the revisionist licensing model focuses primarily on state regulation, there needs to be awareness that no major revisions of this area will occur without the inclusion of the federal regulator, CMS, and that private regulators will not willingly accept the change recommended herein (see Fig. 2).

2.1.1. Refocusing on baseline requirements

Devising a middle pathway does not mean abandonment of traditional regulatory forms; in fact, new governance scholars seem to be in agreement that where appropriate, traditional mechanisms should be retained. Thus, the first element of a revisionist model of licensure is the retention of core entry requirements (Braithwaite *et al.* 2005).¹⁷ In the case of general hospital licensure, the original motivation that sparked passage of such legislation was the need to ensure that acute care facilities met a minimal level of standard in services, operations, organization, and facility adequacy (Hayt & Hayt 1940). The need for entry-level standards is an ongoing one, and in a redesigned regulatory structure, baseline requirements must be retained to insure a general uniformity across the sector, which serves to provide similar, fundamental public health protections. The reality is that the baseline is an evolving area, reflecting continual changes in both the operational and the physical side of the hospital enterprise. Thus, a reconstituted licensing system is an invitation, not to ignore the long-standing entry-level function of licensure, but rather to maintain, and if necessary to strengthen, it. Enforcement of baseline mandates would still require a demonstration of compliance through inspection and reporting, but would move this function into a more fluid regulatory structure; a more collaborative approach could be developed along the lines of what Braithwaite *et al.* (2005) suggest.¹⁸ As such, a constructive dialogue should be promoted between hospitals and regulators, focusing on how an institution could better fulfill its core

obligations. Such a dialogue would factor in changes in the nature of acute care, and the role of new technologies, such as bio-informatics and advanced diagnostics, on basic mandates. Not only would the regulatory discussions around core requirements center on how best to meet such mandates, but they would also include collaboration on the types of measure that must be developed to demonstrate compliance.

2.1.2. Self-assessment problem solving

The second part of a reconstituted licensing model calls for facilities to engage in self-assessments to both identify operational problems and devise pathways to craft solutions for highlighted problems¹⁹ (Coglianese & Lazer 2003).²⁰ This type of self-regulation differs from the development and application of industry standards, such as those promoted by TJC, in that it is a bottom-up process, which originates at the facility level. Each institution will identify a given problem(s), analyze the etiology of the problem, collect supporting data, and craft corrective strategies. Here, too, the regulator has a role to play, which is based initially on collaboration, and providing guidance to facilities in both identifying problem areas and crafting solutions. There is also a possibility to spawn further departure from traditional licensure by mandating that problem-based self-regulation be a process that, in part, extends beyond institutional walls at two levels. At one level, problem identification and solution strategies should encompass all corporate component parts of an acute care entity, licensed and unlicensed. They should extend beyond the traditional inpatient side, and require broad issue evaluations that encompass the continuum of affiliated institutional entities, such as medical office buildings, outpatient clinics, ambulatory treatment centers, and other such facilities within a hospital's corporate umbrella. The four wall approach to hospital licensure largely denies the realities of patient care patterns that track across a continuum of separate facilities and programs, as problems in delivery often relate to continuity of care issues among multiple providers. Problem-based analyses may even extend beyond affiliated entities to encompass networks of care. This would require the hospital in question to identify and correct problems that occur in patient care that involves multiple licensed actors with whom a given institution frequently interacts within its service area.

In the framework of new governance, this phase of the revisionist model draws on Coglianese and Lazer's (2003) management-based regulation model, in that it rests on individual facility planning and data collection as core tenants of the regulatory process.²¹ Like management-based regulation, the self-assessment and problem solving phase would ultimately be focused on improved outputs, and its self-regulatory nature would be spurred on by technical and operational complexities. While the nomenclature presented in the model is one of assessment and problem solving, clearly what institutions need to engage in is self-directed planning. This stage of the revisionist model is not as broad as the Coglianese and Lazer (2003) management-based regulation model, but it clearly entails the transfer of a significant role for achieving public goals to hospitals and placement of risk assessment and control measures with the regulated.

The notion of self-initiated problem solving and correction is not an entirely novel one in the current hospital regulatory context. A relatively small initiative has been launched by CMS known as the Quality Assessment Performance Improvement (QAPI) program. This program requires hospitals to systematically examine quality of care issues and develop institutionally tailored, measurable performance improvement projects.²² The QAPI program falls within the Medicare COP, and is based on both a problem

identification and a correction model. Specifically, the QAPI program entails four sets of requirements: first, the development of an ongoing, hospital-wide program that measures reductions in medical errors; second, the creation of a clearly defined policy for supporting data; third, a priority-setting process for improvements that tracks and analyzes adverse patient events and implements preventive actions; and fourth, the implementation of quality improvement projects proportional to the scope and complexity of hospital services.²³ QAPI certainly is a departure from traditional command and control regulation, and reflects a growing willingness on the part of regulators at CMS to launch a more self-directed approach to identifying and correcting quality problems. QAPI represents a small movement away from traditional, COP elements, and conceivably could allow a certain fluidity in regulation, if federal regulators will allow it to become a more meaningful departure from tradition.²⁴

2.1.3. *Institution specific obligations*

The third element in a revisionist hospital licensing model entails the formulation of an institution specific set of obligations that would be developed in a negotiation process between the state licensing authority and the general hospital in question. Unlike the second part of the revised model, problem identification and solution, which the individual facility largely determines, this element is one that would require significant direction from the regulatory authority. Here, the licensing agency would need to possess a clear vision of a specific institution's role in the state's health delivery system, well beyond compliance with uniform requirements. This process of tailoring specific legal requirements would allow licensure to either extend outside the parameters of established hospital mandates, or change by virtue of institutions falling into additional designated categories, such as being designated a critical access hospital or a CMS center of excellence.²⁵

Negotiated requirements would, in essence, be akin to the development of public performance contracts that establish goals for a given hospital, based on the targeted roles that an institution is required to assume by the state. Such a process would place an obligation on regulators to assume a role more akin to a planning agency; it would require a comprehensive overview of the entire delivery system, as well as the development of clearly thought-out expectations concerning the health needs that a particular hospital's service area must address. Inevitably, objections will surface here arguing that pushing institutions to expand their service mandates will be costly, and that there may be inequities across institutions in levels of responsibility required. Thus, regulators will need to be sensitive to financial realities and provide hospitals with assistance in securing adequate funding for new service initiatives. In addition, CMS must be encouraged to cooperate with a process that allows for the creation of tailored institutional requirements. This may be an arena for providing institutional reimbursement incentives through a "pay for performance" type scheme tied to a hospital meeting special state service goals (Rosenthal & Dudley 2007).

2.1.3.1. *Charity care.* Two examples can be highlighted that demonstrate tailored hospital mandates in the areas of charity care and institutional health planning. Charity care has been a major point of controversy in the US hospital arena for the past few years, stemming from critical assessments of the failure of non-profit hospitals to meet community benefit obligations required under local, state, and federal tax laws (Sturges 2006). In response to such deficiencies, a number of state attorneys general, as well as

the federal Internal Revenue Service (IRS) have increased oversight in this area. In 2006, the IRS launched a large investigation of American hospitals, requiring 600 institutions to complete a detailed survey reviewing key aspects of the IRS's community benefit standard (Bricker J & Eckler J 2006, unpublished data).²⁶ Current hospital investigation is directed toward assessment of institutional performance in a number of areas, including patient demographics, reasons for denial of care, amounts of uncompensated care, billing practices, involvement in medical research programs, and medical education and training.²⁷ This seemingly provides a more detailed sense of what constitutes a community benefit. Not surprisingly, several hospital organizations have developed new standards in the community benefit area to address the current issues being investigated, and to circumvent further government enforcement in this area.²⁸ The fact is, however, that beyond a formulistic approach to measuring dollars actually spent on charity care, there is still a fair degree of ambiguity as to what a community benefit really is.

The area of community benefit provides an ideal situation for state regulators to negotiate specific agreements with hospitals to target their efforts in this area into certain types of activity. It seems clear that the environments within which hospitals function vary by location and populations served, and such differences should be seen as instrumental variables in developing and assessing a meaningful application of a community benefit standard. As such, a licensing authority could move beyond a formulistic approach and set specific requirements for charity care based on the needs of the local community served. A more meaningful community benefit standard could be linked to public health needs and focus on assistance with matters such as school health, elder care, diet and nutrition counseling, and health education by incorporating specific targets into the institution's licensing obligations. Where there are significant numbers of uninsured individuals in a given community, licensing authorities should work with respective institutions to devise particular strategies for providing care, as well as to assist individuals in obtaining insurance coverage. In addition, efforts by licensing authorities would target institutions in more affluent areas to partner with hospitals serving special needs populations as a condition of licensure and community benefit obligation. In a revisionist hospital licensing model, the creation of tailored obligations to provide delineated community benefits, while directed by regulators, should not be viewed as a one-sided process, but may entail negotiated agreements that reflect public needs, and result in the creation of viable institutional obligations.

2.1.3.2. Health planning. A second example of tailored hospital mandates can be found in the area of health planning. There has always been a close nexus between licensing laws and mandated health planning as state certificate of need (CON) laws were developed, either as an add-on to licensure, or directly related to the licensure process (Capron & Birnbaum 2007). Under CON laws, covered facilities are required to obtain special approval from state authorities for various expansions, new construction, and other capital improvements. Many CON laws have been repealed, as they have been subjected to intense criticism for being overly bureaucratic and largely ineffective in forging a more rationalized system; furthermore, free market proponents see the laws as unnecessary (Crouse 2007).²⁹ What seems largely lost in the past debates over the efficacy of certificate of need laws, and current enforcement battles, is the fact that these laws were designed to facilitate health planning at the institutional level. While the health planning movement, which encompassed CON, was locked into a complex web of bureaucracy, a key goal was to foster a rational health system, responsive to community needs through

planning – an idea not without merit (Nodzinski 1998).³⁰ In essence, the planning function at the institutional level has been lost with statutory repeals, and, in jurisdictions that still retain these laws, subsumed by capital funding approval processes. Hospital-based health planning could be reinvigorated by allowing the licensing authorities the ability to mandate special planning activities on the part of licensees. For example, tailored community benefit obligations could be negotiated between regulators and individual facilities. Licensing authorities could establish requirements that given hospitals devise plans to confront particular challenges in their service areas (that may include charity care), or develop strategies anticipating changes in institutional demands, such as the need to update information technologies, or meet broad challenges caused by shifts in patient demographics. Planning mandates, attached to licensure, may also require that a given institution engage in such activities in conjunction with other licensed facilities, and include community representatives in these processes as well.

2.1.4. Changing the oversight

The fourth element of a revised hospital licensing model concerns a change in the structure of regulatory oversight, as opposed to an alteration of the format of regulation. The current system, which entails tripartite organizational oversight, discussed earlier in this article, is not an effective regulatory regime, even if all three actors (CMS, state agencies, and TJC) reach some type of operational balance. The fact is that hospital licensing is, first and foremost, a state-based regulatory activity, fundamental to the exercise of basic police power functions. The federal role in hospital regulation, designed to safeguard its interests as the sponsors of public insurance programs, sprang from concerns over state inadequacies, but becomes particularly redundant in settings where states can reform licensing functions in ways that make these procedures both comprehensive and current. TJC's accreditation role is based on its historical engagement with the hospital field, a distrust of state capabilities, and acquiescence on the part of the federal government to allow for private sector regulation of this area. Yet, as noted, private accreditation is a matter of controversy and increasing doubt.

Hospital licensing, and related standard setting, should be streamlined as a fee-based, state-controlled process. Moreover, while state regulators may seek the assistance of other entities with various aspects of licensure, the legislature should not formally transfer public authority to private regulators via "deemed status." In turn, Medicare/Medicaid laws should be changed to allow the state licensing standards to be the entry requirements for participation of hospitals in these two federal programs, in effect delegating the COP function in its entirety to states with a requisite increase in federal transfer payments for this expanded oversight role. The fact that CMS would transfer COP development and oversight does not eliminate the federal agency from involvement and possible intervention into hospital licensure.³¹ Rather, as the sponsor of Medicare, and in new governance parlance the meta-regulator, CMS would be involved in monitoring state licensing authorities, by setting regulatory goals/objectives for the process, measuring performance, and conducting fiscal oversight. If a state fails in its tasks of hospital regulation, meta-regulation authority would allow CMS to intervene and trump state law in order to reinvigorate hospital licensing processes. Outside of crisis situations, CMS would be cast in an advisory role, and work with states in developing other elements of the model, namely baseline standard setting, problem identification and planning, and crafting institution specific projects. None of the revisionist licensing

model elements should have a permanent status; the federal meta-regulator should insist that state authorities and industry experts frequently review the requirements and update them as needed.

As noted, neither TJC nor AOA would be empowered to act as a private accreditor with “deemed status,” but their continued involvement with hospitals could serve as evidence to verify that entities are meeting new, flexible state mandates contained in a revised licensing model.³² Private accrediting bodies can serve in a consultative role, providing assistance to individual facilities with both the problem identification and the solution phase of the proposed licensure model. Additionally, the organizations can aid in the development of strategies to meet targeted regulatory objectives called for in the third phase of the model. It is also important to note that state authorities must retain the more traditional punitive aspects of licensure (i.e. fines, suspension of license) for the most serious rule violations, but even here, state regulators must be afforded the opportunity to impose flexible and creative solutions in addressing hospital deficiencies.

3. Barriers to a revisionist general hospital licensing model

The revisionist licensing scheme contains various elements from emerging reform models such as community focus, public participation, collaboration, self-regulation and planning, and meta-regulation, as well as a continued, significant role for regulators. These factors combine to constitute a major departure from the current tripartite licensing arrangements. The inevitable question that must be addressed concerns the feasibility of the changes recommended in the revisionist licensing model. The practicability question is particularly apt as the hospital licensing area was selected as the framework for a new governance approach, in part because seemingly it would be easier to spark change in this context, rather than the promotion of a more radical regulatory overhaul.

It is unlikely that any alteration of established health care regulations will be easily accomplished in the US or elsewhere, particularly if the area is not seen as being at a crisis point. As previously noted, hospital licensure, and the accompanying certification and accreditation processes, are not static. Opponents would inevitably argue that changes in hospital regulation, if needed, could be made without scrapping a highly established regulatory framework. There is no evidence of public pressure for altering the rather distant processes of hospital licensure, and entrenched interests, on both the public and private side, will likely oppose any major alterations of the status quo.³³ While some states have been active in general hospital licensing law changes, others are dependent on TJC accreditation, as most state agencies are short on both human resources and financing. State authorities often find compliance with current licensing mandates problematic, so the adoption of extended responsibilities through a revisionist licensing model would require a meaningful increase in resources, through an institutional fee system, as well as expansion in state and federal funding. Both financial solutions are problematic. Recently, CMS has embarked on making changes in the Medicare COP for hospitals, and thus may be reluctant to purposefully cede greater authority back to the states.³⁴ Undoubtedly, TJC will mount significant opposition to a revised licensing model, as it has proven to be a resilient regulatory force and has engendered far greater dependency in the field than the hospital community may admit (Burda 2002).

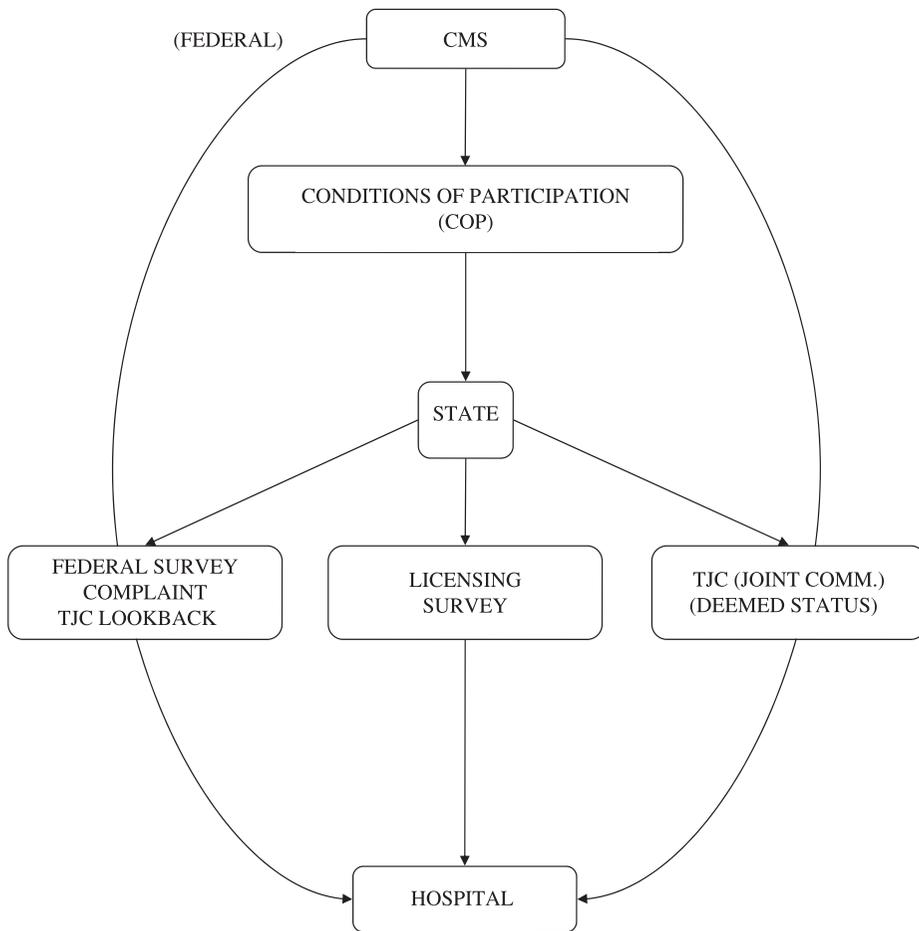


Figure 1 Current tripartite hospital licensure.

The biggest obstacle to altering the general hospital licensure model along the lines proposed is perhaps neither bureaucratic entrenchment nor finance, but rather the underlying lack of trust between the hospital industry and the regulatory community.³⁵ While an accounting of the erosion of trust between regulator and regulated in the hospital context is beyond the scope of this article, even a casual review of enforcement in this area will lead to a conclusion that elements of distrust are deeply rooted in the various regulatory schemes that underpin hospital oversight. This is not to say that problems of poor compliance, or even fraudulent practices, do not exist in the hospital sector, but changes along the lines proposed in this article, which rest on collaboration, and rely to an extent on self-regulation, necessitate a high degree of trust among the respective actors. Complicating the requisite need for trust is the reality that the regulatory community dealing with hospitals is not a unitary one; strong disagreements will emerge in the ranks of regulators, splitting those who are willing to be innovative from bureaucrats and prosecutors wedded to command and control mandates and strict enforcement.

Undoubtedly, a certain element of distrust on the part of regulators is justified. It is manifested in new governance thought, evidenced, for example, in responsive regulation

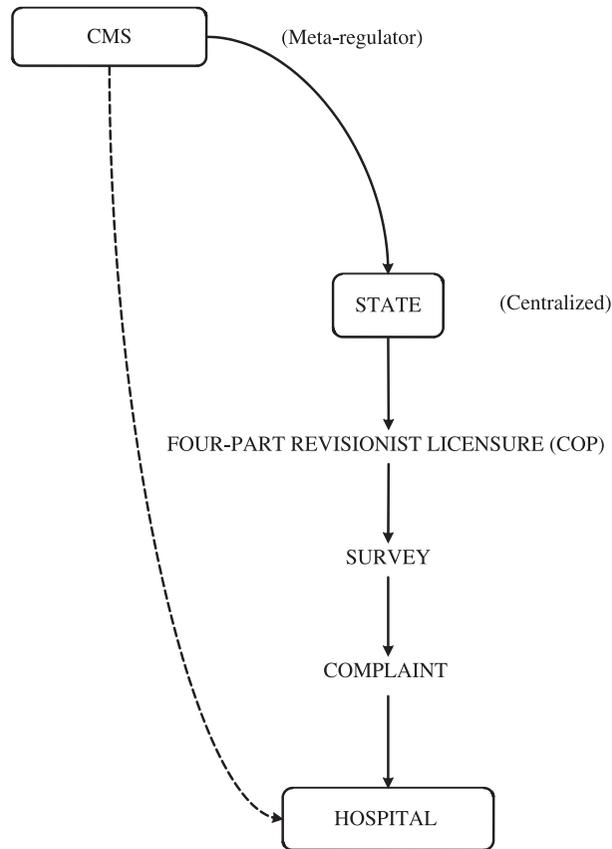


Figure 2 Revisionist model of hospital licensure.

through the development of a regulatory pyramid, relying ultimately on government power (Braithwaite *et al.* 2005). The question is whether or not the more creative aspects of new governance become only a veneer for traditional enforcement schemes, which reside in the wings, and rapidly emerge center stage at the first signs of failings in any new regulatory order. In this context, a careful balance needs to be struck that allows a new licensing model (or any other new regulatory scheme for that matter) an opportunity to be adequately tested – this will undoubtedly require a willingness to waive traditional rules in favor of trying to achieve a more desirable regulatory environment. While it is unlikely that all of the entrenched interests in hospital regulation, which are considerable, will endorse the licensing model presented in this article, such a proposal cannot succeed unless there is sufficient trust among the requisite parties.

Assessment of the current hospital oversight landscape does lead to a reasonable conclusion that regulators at federal and state levels are willing to allow more creative oversight processes. This is evidenced by tolerated changes in delegated, private regulation, and to a lesser extent in small efforts, such as the QAPI, described herein.³⁶ Some in government will see the fluidity in the revisionist licensing model as a way to overcome the inertia of command and control, while still allowing CMS oversight and prosecutorial discretion. States will no doubt be challenged to assume *de jure* authority to centralize hospital oversight, but consequential efficiencies in operations will be

enhanced broadly by greater planning and priority setting, which are foundational processes inherent in a revisionist licensing model. The resource issue will be a central challenge for state bureaucracies, but as hospitals would be freed from costly TJC accreditation processes, new funds would become available to support a state-based fee system. Moreover, it is likely that charges for public evaluation will be less than current accreditation costs. Hospitals, as the subjects of regulation, currently bear the burden of the layered command and control system most directly, and seem highly receptive to more flexible, targeted oversight mechanisms (AHA 2002). Certainly, licensing changes will trigger operational adjustments and new compliance requirements, but movement to tailored mandates under a revisionist model should provide meaningful direction, and overcome ambiguities in areas such as community benefit obligation.

Conclusion

This article is driven by a realization that the current command and control system of health regulation is flawed and that new governance opens options for a more efficient, collaborative process between government and the field. The reform model posited herein draws on alternative regulatory approaches in a traditional venue, hospital licensure, and as such offers a contextual framework for reform efforts in a highly applied setting. This article offers a model for change that is not only applied, but is integrated into current regulatory mandates, as opposed to a whole cloth reform proposal. The four elements of a revisionist licensing model (baseline review, problem analyses, tailored regulation, and oversight revision) capture elements of emerging regulatory reform models but do not draw on any one specific template. More specifically, the lesson for the regulatory reform of the hospital sector is that reform initiatives don't need to be built from the ground up and a current modality, even a rather old one like licensure, may be readjusted in creative ways, rather than discarded as no longer relevant.

It is equally important to note in this conclusion that the proposal for licensure reform involves alteration of industry mandates in a highly significant context. Virtually all elements of acute care institutional operations are touched by licensure, as this regulatory process impacts the full range of hospital services, and frequently must be readjusted because of ongoing changes in this area. The proposed revision in hospital oversight is offered with a keen awareness that enthusiasm for reforming an existing regulatory mechanism must be tempered by an understanding of the inherent difficulties that will emerge in altering a long-standing status quo. The politics of licensure, involving three sets of regulators, a fluid industry, and a regulatory apparatus not fatally broken, will make a case for any change here difficult. Still, no type of reform in health care will occur easily, and without doubt, the movement to a revisionist licensure model will be characterized by both unique and general sector challenges, faced in any new governance proposal. In order for the changes suggested herein to occur, key parties must view licensing reform along the lines argued for in this article as an opportunity to address regulatory shortcomings and recognize that process reform opens avenues for participation, and ultimately more relevant and substantive oversights. There are no magic bullets in health care reform, but the area's increasing difficulties call for creativity, and demand consideration of multiple approaches to reform of which a revisionist hospital licensing model should be one.

Notes

- 1 See also Anon. (1951).
- 2 This article discusses the American Hospital Association model bill.
- 3 For example, see generally Council on Medical Education and Hospitals of the American Medical Association (1932), which is the 11th annual presentation of hospital data by the that contains the AMA criteria for registration of hospitals. The AMA registration criteria included organization, staff, nurses, records, pathology, radiology, and ethics.
- 4 See also Anon. (1951).
- 5 See also Hayt and Hayt (1940).
- 6 *Illinois Hospital Licensing Act*, 210 Ill. Comp. Stat. 85 (2004). This may have certain unique characteristics as state laws in this area do have. It is nevertheless characteristic of laws in this area.
- 7 In fact, some of the changes made in licensing laws have been rather substantial; see, for example, the revised hospital licensure regulations issued by the Georgia Department of Human Resources in 2002, Ga. Comp. R. & Regs. 290-9-7-.03, 290-9-7-.40 (2007).
- 8 *Social Security Act of 1965*, Pub. L. No. 89-97, 79 Stat. 313 (1965).
- 9 42 U.S.C. § 1395x(c), 1395b (2000).
- 10 States have annual agreements with CMS to conduct Federal Surveys, respond to complaints and “Look-Back” at a number of TJC Accreditations.
- 11 Interview by author with Enrique Unanue, Deputy Director, Illinois Office of Health Care Regulation, 31 October 2006.
- 12 Interview by author with Enrique Unanue, Deputy Director, Illinois Office of Health Care Regulation, 31 October 2006.
- 13 Again, see the *Illinois Hospital Licensing Act*, 210 Ill. Comp. Stat. 85 (2004), which has been amended to reflect current challenges faced by hospitals.
- 14 Ironically, The Joint Commission (2008) with its sentinel event program which predated the IOM Report, *To Err is Human* (Kohn *et al.* 1999), was actually a leader in recognition of the medical error issue and had prior to government devised a means of addressing the issue.
- 15 US Department of Health and Human Services, Centers for Medicare and Medicaid (2006). This application was subsequently denied but interest in using the ISO 9001 standards for hospital accreditation continues. See also Blum (2005).
- 16 These appear to be general goals, characteristic of regulatory reform initiatives.
- 17 US Department of Health and Human Services, Centers for Medicare and Medicaid (2006).
- 18 US Department of Health and Human Services, Centers for Medicare and Medicaid (2006).
- 19 US Department of Health and Human Services, Centers for Medicare and Medicaid (2006).
- 20 This reflects a new governance approach that draws in part from management-based regulation.
- 21 US Department of Health and Human Services, Centers for Medicare and Medicaid (2006).
- 22 Conditions of Participation for Hospitals: Quality Assessment and Performance Improvement, codified 42 C.F.R. 482.21 (2006).
- 23 Conditions of Participation for Hospitals: Quality Assessment and Performance Improvement, codified 42 C.F.R. 482.21 (2006).
- 24 There is a strong bias within CMS toward prescriptive command and control regulation that is bordered not by flexibility but toward a prosecutorial approach to enforcement.
- 25 See generally 42 CFR 485.601 *et seq.* (2002), providing details on critical access hospitals and 42 CFR 52-1(a)], concerning grants to be designated a hospital clinical center of excellence.
- 26 See Kilworth (2006). It is interesting to note that the federal community benefit standard articulated in Revenue ruling 69-545 deals with charity care only in the context of emergency room care, but has become a dominant element of focus in this area.
- 27 IRS form 13790, OMB no. 1545 (2005).
- 28 For an example, see Catholic Health Association (2007) Community Benefit page. See also Dean and Trocchio (2005).

- 29 See also US Federal Trade Commission, US Department of Justice (2004). This report recommended that laws be repealed in favor of a competitive marketplace.
- 30 In this piece, Nodzinski argues that health planning can be more than a review and approval for capital expenditures but could be used also as a mechanism to evaluate community benefits and correlate much more directly to population needs.
- 31 Changes in Medicare law entail multiple amendments of statutory law, as well as rules and regulations.
- 32 In a sense, the private sector accreditors, TJC and AOA, could play a role in hospital regulation somewhat akin to the role of certification agencies in the ISO review process.
- 33 In fact, engaging the public in determining the community obligations of a general hospital becomes a compelling reason for promoting regulatory changes in this area.
- 34 Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders: Securing Medications: and Postanesthesia Evaluations, 71 FR 68672 (27 Nov 2006) (to be codified at 42 C.F.R. 482).
- 35 The lack of trust in health care delivery generally has become a major focal point for analysis; see Shore (2006).
- 36 Conditions of Participation for Hospitals: Quality Assessment and Performance Improvement, codified 42 C.F.R. 482.21 (2006). Certainly the desire to create new, more effective regulatory processes is a long-standing one in policy circles; see Bernstein M (1961). In government, regulatory reform is also a persistent theme and has sparked changes in administrative law, see Stewart (2003), and ongoing efforts by the bureaucracy, see DHHS (2005).

References

- AHA (American Hospital Association) (2002) *Task Force on Regulatory Relief and Reform*. AHA, Washington, DC.
- Anon. (1951) What States License Hospitals? How are They Progressing with Hill Burton Construction? *Hospital Management* 71 (Mar), 48–50.
- Bernstein M (1961) The Regulatory Process: A Framework for Analysis. *Law & Contemporary Problems* 26, 329–346.
- Blum JD (2005) Combating Those Ugly Medical Errors: It's Time for a Regulatory Makeover. *Widener Law Review* 13, 53–76.
- Braithwaite J, Healy J, Dwan K (2005) *The Governance of Health Safety and Quality, Australian Council for Safety and Quality in Health Care*. Commonwealth of Australia.
- Burda D (2002) Déjà Vu All Over Again: Joint Commission History Casts Doubt on Sincerity of Its Newest Makeover. *Modern Healthcare* Oct 14, pp. 22.
- Capron A, Birnbaum I (2007) *Treatise on Health Care Law*. Matthew Bender, Newark, NJ.
- Catalano K, Oglesby L (2006) TJC Under Fire Again: JCR is the Issue. *Hospital Peer Review* 1 Jul, 93–94.
- Catholic Health Association (2007) A Guide for Planning and Reporting Community Benefit. [Last accessed 30 Jan 2008.] Available from URL: <http://www.chausa.org/communitybenefit/guide>.
- Coglianesi C, Lazer D (2003) Management-based Regulation: Prescribing Private Management to Achieve Public Goals. *Law & Society Review* 37, 691.
- Council on Medical Education and Hospitals of the American Medical Association (1932) Hospital Services in the United States. Tenth Annual Presentation of Hospital Data by the Council on Medical Education and Hospitals of the American Medical Association. *Journal of the American Medical Association* 96, 1009–1022.
- Crouse A (2007) *Report of the Missouri Senate Interim Committee on Certificate of Need of Missouri*. State of Missouri, 17 Jan 2007, Jefferson City, MO.
- Dean N, Trocchio J (2005) Community Benefit: What It Is and Isn't. *Health Progress* 86 (No. 4, Jul/Aug), 22–26.

- DHHS (US Department of Health and Human Services) (2005) HHS Works to Improve Health Care Regulatory Process. News Release, 5 Nov 2005.
- Hayt E, Hayt L (1940) *Legal Guide for American Hospitals*. Physicians Record Company, Berwyn, IL.
- Katzfey R (2004) TJC's Shared Visions—New Pathways: The Hospital Survey and Accreditation Process for 2004. *American Journal of Health System Pharmacy* 61, 1358–1364.
- Kilworth AR (2006) IRS Begins Community Benefit Inquiries – Hospitals Contacted. [Last accessed 18 Dec 2007.] Available from URL: <http://www.bricker.com/Publications/articles/955.asp>.
- Kohn LT, Corrigan JM, Donaldson MS (Eds) (1999) *To Err is Human: Building a Safer Health System*. Committee on Quality of Health Care in America, Institute of Medicine. National Academy Press, Washington, DC.
- Nodzinski T (1998) Regulating Managed Care Coverage: A New Direction for Health-planning Agencies. *Annals of Health Law* 7, 1.
- Roberts J, Coale J, Redmond R (1987) A History of the Joint Commission on Accreditation of Hospitals. *Journal of the American Medical Association* 258, 936.
- Rosenthal MB, Dudley RA (2007) Pay For Performance: Will the Latest Payment Trend Improve Quality. *Journal of the American Medical Association* 297, 740–744.
- Shore D (2006) *The Trust Crisis in Health Care: Causes, Consequences and Cures*. Oxford University Press, New York, NY.
- Stewart R (2003) Administrative law in the 21st Century. *New York University Law Review* 78, 437–464.
- Sturges P (2006) Review of Community Benefit Standard Explores Concerns about other Approaches. 15 *BNA HLR* 1093.
- The Joint Commission (2008) Sentinel Event. [Last accessed 30 Jan 2008.] Available from URL: <http://www.jointcommission.org/SentinelEvents/PolicyandProcedures>.
- US Department of Health and Human Services, Centers for Medicare and Medicaid (2006) Medicare and Medicaid Programs; Application by the TUV Healthcare Specialist for Deeming Authority for Hospitals. *Federal Register* 71 (27 Jan), 4584.
- US Federal Trade Commission, US Department of Justice (2004) *Improving Health Care: A Dose of Competition*. US Government Printing Office, Washington, DC.
- Whitehall A (1953) Why Hospitals Should Be Licensed? *Texas Hospitals* 9, 6–7.

Laws cited

- Federal Hospital Survey and Construction Act, 42 U.S.C. sec.291 et seq. (2007).
- Illinois Hospital Licensing Act, 210 Ill. Comp. Stat. 85 (2004).
- Social Security Act of 1965, Pub. L. No. 89–97, 79 Stat. 313 (1965).
- 42 U.S.C. § 1395x(c), 1395b (2000).