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John D. Blum

*Loyola University Chicago, School of Law, [jblum@luc.edu](mailto:jblum@luc.edu)*

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## Finding a New Regulatory Pathway for the Old Labyrinth of Health Planning

*John D. Blum, J.D., M.H.S.\**



The past twenty-five years have seen a proliferation of health laws and regulations that are indicative of the complexities of a health delivery system driven by science and technology, and often shaped in unintended ways by the very laws and policies designed to control it. The history of current health insurance reform debates underscores the massive challenges of crafting legislation in health that expands coverage while balancing the two other elements of the health triad: cost and quality. While a vision of what the US health system should be remains illusive, there is no hesitation on the part of policy makers, legislators and regulators to continually conceptualize and proliferate new laws to address the current problem of the day, and seemingly spawn an endless sea of regulatory acronyms. This essay is written from an observation sparked by working in this field for many years; namely, that there are really very few ideas in health regulation that are novel, and what passes for new, innovative approaches is often a mere iteration of prior ideas and programs. The insight that new ideas frequently are recycled notions from the past is not rooted in a critical vein, but rather from a conviction that returning to past ideas can actually be a progressive step, and that those past efforts are often too quickly discarded as the victims of shifts in regulatory ideology. This essay will make the argument that two ideas from the past should be embraced by health regulators, one to foster a more rational vision of the delivery system, and the other to improve the administrative processes to more effectively actualize a coherent regulatory vision. The first topic calls for a return to the halcyon days of 1970s regulatory philosophy, health planning, and the second lies in the more jurisprudential area of administrative law, the adoption of new governance, management-based regulation or responsive regulation as a mechanism to revitalize health planning.

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\* John J. Waldron Research Professor, Loyola University Chicago School of Law.

Historically, health planning at both the federal and state levels emerged from a concern that the market was not an adequate vehicle to control the run away expansion of health facilities and the commensurate costs associated with such expansions. These concerns date back to 1946 with the enactment of the federal Hill-Burton program that provided funds for new hospital construction, contingent on the adoption of a state health plan to evaluate the respective projects<sup>1</sup>. Subsequent to Hill-Burton, the 1966 Public Health Service Amendments created state and local planning agencies that were each individually mandated to create plans to oversee health care facility growth, but these entities lacked the statutory power to implement their suggestions. In 1964, New York State enacted the first Certificate of Need law, quickly followed by Rhode Island, Maryland and California. The state-based Certificate of Need laws regulated facility capacity and service changes and were enforced through denial of an operating license, court injunctions and fines. In the late 1960s, area-wide planning was introduced through voluntary efforts to encourage regional collaborative planning under amendments to the U.S. Public Health Act (section 318): the Regional Medical Program was created, with a focus on heart disease, cancer and stroke. In 1972, Congress created the Section 1122 program that required participating states to evaluate Medicare capital expenditures, with the potential of payment denial for failure to comply. These efforts culminated in 1974 with the passage of the federal National Health Planning and Resource Development Act (NHPRDA) that mandated states to enact Certificate of Need Laws or have in place some mechanism for review of building projects and capital expenditures.<sup>2</sup> The NHPRDA was unique in that it is a piece of federal health legislation that in its preamble actually recognized health as a basic right of all citizens but from an operational standpoint attempted to create a single unitary network of state and regional agencies to engage in health planning, resource development, and service review, and expand such efforts outside hospital settings. In reality, the NHPRDA created an elaborate network of new regional planning entities referred to as Health System Agencies (HSAs) that were intended to work with newly mandated state wide actors. While valuable studies of regional health activities emerged, particularly in the data collection area, the bureaucratic structure which the 1974 law created was overwhelmingly complex and duplicative of state initiatives in the area. The federal mandate spurted and never reached its full potential, because it was far too bureaucratic and multi-layered to work efficiently. More often

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1. Fred J. Hellinger, *The Effect of Certificate of Need Laws on Hospital Beds and Health Care Expenditures- An Empirical Analysis*, 15 AM. J. OF MANAGED CARE 737, 737-44, (Oct. 2009).

2. Pub. L. No. 93-641.

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than not, project review and evaluations became mere regulatory paper tigers, mandating complex applications and resting on suspect planning measurements such as bed need criterion. Many state boards were dominated by political considerations, where project approval was the norm and the process was marked by classic cases of legislative interference and judicial challenges. Questions of affectedness of C.O.N. laws hounded the state programs from their inception, and some argued that the bureaucracy of review and approval caused delays that resulted in increasing costs.

By the time the Regan administration came into power in the early 1980s, three states, Utah, Idaho, and New Mexico, repealed their C.O.N. laws without any subsequent federal sanctions. In 1986, Congress struck down the mandate that tied the existence of C.O.N. laws to receipt of federal funds and ten additional states repealed their respective review programs.<sup>3</sup> Ironically Louisiana, the one state, that never had a C.O.N. mandate and only had an 1122 program, actually enacted a C.O.N. law in 1991. Interestingly enough, thirty-six states still retain C.O.N. laws in some manner, and these pieces of legislation are not dormant, but rather continue to be amended on a regular basis.<sup>4</sup> Typically the threshold amounts for mandatory review have been increased, but the scope of state reviews have been expanded to include long term care, ambulatory health programs and particular pieces of technology.

In 2010, now in the shadow of health reform, the merits of state C.O.N. laws remain points of contention. In recent years, as might be expected, numerous studies have been conducted on the merits of these laws, with results that are less than conclusive. For example, in a 2002 JAMA article, a study was reported that medical outcomes for coronary artery bypass graft surgery were better in states with C.O.N. laws.<sup>5</sup> On the other hand, in a policy report on competition in health care, the US Federal Trade Commission and the Department of Justice concluded that C.O.N. laws were ineffective and should be abolished in favor of competitive health markets, as more effective cost and quality control mechanisms.<sup>6</sup> Ironically, hospital associations have supported C.O.N. laws as a viable mechanism to control costs as opposed to organized medicine that views the process as a bureaucratic structure that stifles innovation and frustrates the

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3. Hellinger, *supra* note 1.

4. National Conference of State Legislatures, *Certificate of Need: State Health Laws and Programs: Certificate of Need*, updated May 2009, available at <http://204.131.235.67/programs/health/cert-need.htm>.

5. Mary Vaughan-Sarrazin, Edward L. Hannan, Carol J. Gormley, and Gary Rosenthal, *Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States With and Without Certificate of Need Regulation*, 288 JAMA 1859-66 (2002).

6. U.S. DEP'T. OF JUSTICE AND U.S. FED. TRADE COMM'N, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, CERTIFICATE OF NEED Chapter 8 (2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerept.pdf>.

proliferation of ambulatory care programs, particularly specialty hospitals. A number of states have launched studies of the future of C.O.N. laws, and to an extent the results of these efforts mirror the regulatory biases of the respective jurisdictions. Two reports of particular note come out of Washington State and Illinois, respectively.<sup>7</sup> While the two reports contain features unique to the health systems in these states, three major commonalities emerge. One common feature is the recognition that C.O.N. procedures need to be streamlined but also focused on a wider array of health actors. Second, the two reports emphasize that state agencies must be more focused on special needs populations and on the institutions that serve as the state's safety net. Third, and perhaps most notably, both reports call for C.O.N. to be refocused on its core mission in the area of health planning.

Somewhere along the journey of C.O.N. laws, these statutes became dominated by process review and evaluation, and the core function of creating state and regional health plans dropped from the agenda of these agencies, or planning was turned over to state bureaucrats whose best efforts were foiled by political realities. Even in the face of the best systems of evaluation, the regulatory vision was myopic and often resulted in piecemeal regulatory oversight that too often did little to prevent a highly disjointed, uncoordinated health system. Powerful market forces trumped health planning and, in the face of these regulations, large powerful hospital groupings emerged, proverbial bigger ships sailing on their own expanding bottoms in a process dominated by politics. Institutional dominance prevailed and was not foiled by health planning, and innovations like clinical integration emerged as tools not to respond to community need, but rather as processes designed to insure competitive advantage and market dominance. The health planning movement did little to stem the tide of eroding municipal and county health systems that were all too often victims of incompetent local politics and epicenters of patronage, strangled by unions bent on retaining jobs, rather than promoting public health.

No doubt there will be those who will argue that cost and quality problems stem from over regulation and that the last thing needed is a bureaucratic pathway for health planning. Others may argue that it is legal constraints, particularly from antitrust laws, that have kept institutions from pursuing more unified, rationalized visions of regional health delivery. Still others may point to New York State where the so-called Berger Commission took over health planning and actually has become active in

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7. SENATOR SUSAN BARRETT & REPRESENTATIVE LISA DUGAN, THE ILLINOIS TASK FORCE REPORT ON HEALTH PLANNING REFORM, *available at* <http://www.idph.state.il.us/tfhpr/reports/TFHPR%20Final%20Report.pdf>; *see also* COMM'N ON THE EFFICACY OF THE CON PROGRAM, FINAL REPORT: AN ANALYSIS AND EVALUATION OF THE CERTIFICATE OF NEED IN GEORGIA (2007) (an example of recent C.O.N. analysis).

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closing and downsizing facilities as far too intrusive.<sup>8</sup> Or some many see what is transpiring north of our border in Ontario: the adoption of Local Health Integration Networks (LHIN), mandating hospital accountability agreements for uses of public monies as being counterproductive to creativity, and even endangering fiscal viability.<sup>9</sup>

It would be naïve to argue that interjecting more meaningful health planning into state bureaucracies will solve all the ills of the delivery system, but if structured in a meaningful way, health planning could make our current system far more rational and, in turn, more responsive to public health needs. The argument for revitalized health planning herein has seven components. To begin with, as sadly demonstrated in the current national health reform debate, there is very little vision concerning what our health delivery system should look like. To a large extent, policy makers, legislators and bureaucrats have been co-opted by the major providers and private payors, and most ideas that come from government, such as Accountable Health Organizations (AHOs) or Comparative Effectiveness Research (CER), originate in the private sector, seized on by the public sector as magic bullets.<sup>10</sup> System reinvention is challenging with ongoing innovations in science and technology, but the goal of universal coverage, as desirable as it is, needs to be placed in a context that is meaningful at both the macro and micro levels.

Secondly, health planning is necessary, because a convincing case has not been made that competition saves money or improves quality. All too often, regulation is a response to market failures or abuses, but without strategic planning backing regulatory responses, such interventions are stop gap measures that often only invite abuses in other areas of the delivery system. A third rationale for planning rests on the fact that hospitals and other health provider entities are independent actors competing for dominance, and so have little reason to be cooperative with one another. Hospital leaders and governing boards are not rewarded for building relationships with competitors, but rather devise plans around the success of their institutions and systems. The fourth reason for government-initiated health planning, overcoming antitrust law barriers, is related to the insular nature of how health institutions function and the need for a public

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8. Berger Comm'n Health Status Report, Berger Commission Measures Implemented, State Health Commission Reports (July 2, 2008) (on file with author).

9. David Reeleder, Vivek Goel, Peter A. Singer & Douglas Martin, *Accountability Agreements in Ontario Hospitals: Are They Fair?*, 18 J. PUB. ADMIN. RESEARCH & THEORY 161 (Jan. 2008).

10. MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO CONGRESS: IMPROVING INCENTIVES IN THE MEDICARE PROGRAM, Chapter 2 (June 2009); see also John K. Ingelhart, *Prioritizing Comparative Effectiveness Research—IOM Recommendations*, 361 N. ENG. J. MED. 325, 325-27 (July 23, 2009).

authority to take a leadership role to forge institutional linkages that maybe impossible to create. Fifth, a government health plan is needed to draw all licensed entities into safety net responsibilities. Treating the poor should be an obligation of licensure and not left to the politics of local governments or the idiosyncrasies of the laws of tax exemption. The sixth component of health planning is the need to recognize licensed complementary and alternative medicine (CAM) providers in the planning process, because there has been a proliferation of such providers, many of whom practice in clinic settings. While CAM may still evoke controversy in some sectors, these eclectic bodies of licensed providers have become part of the fabric of our established health system and need to be factored into a global vision of health delivery. Finally, the seventh reason for revitalized state health planning is the need for a central point to coalesce health matters in a broad sense, as a template to bring together not only traditional institutional provider matters, but also to act as a coordinating vehicle for linkage to broader public health concerns and regulations. There is no doubt that moving a state into a more aggressive health planning role will require increased resources and capacity, but here resources should be required to finance this process and to act as regulatory partners with state planners.

Enhanced health planning could be an important vehicle for underpinning a more rational and effective health system, but a second equally helpful change resides in the more obscure realms of administrative law. Typically, federal and state health legislation is implemented through a traditional rule making procedure delineated in administrative procedure laws and policies. The expansion of health laws, sparked by an ever complex delivery system, has resulted in a massive rulemaking enterprise dominated by command and control processes that annually adds voluminous amounts of new regulatory requirements. Some regulations may come and go, but more often the proliferation of mandates is phenomena of layering in which new mandates are merely added on to existing regulations. Problems abound in health care, and the usual response of legislators and bureaucrats is both to expand existing regulatory initiatives, as well as pass new laws, rather than merely revamp existing structures. An example of dysfunctional regulatory creep can be seen in the area of institutional licensure where frequent amendments are made, but the process itself is underutilized and viewed with skepticism, so such extensions to this body of law are rarely seen as adequate in areas such as patient safety or charity care. In addition, health care is heavily subjected to voluntary or private regulation, as groups like The Joint Commission (TJC) and the National Quality Association (NCQA) spawn separate mandates and have considerable influence over entities which they oversee as well,

adding to regulatory burdens.<sup>11</sup> It maybe naïve to think that revised health planning will stem the tide of regulatory creep, but, at the very least, a more explicit vision of the health system can provide a framework for coordination and integration that is desperately lacking in the current context.

This reality of expansiveness has been critiqued widely, and there are frequently lamentations, often from the health field, to abate this seemingly endless rule proliferation. It is unrealistic, however, given the public needs in health and the likely growth of government involvement in health reform, to expect regulatory expansion to abate. Rather, serious consideration should be applied to the processes of health regulation and to exploring reforms in the rulemaking arena that not merely reduce the volume of mandates, but make rule making more effective. The challenges of the regulatory state spill beyond the US borders, and a global legal movement has been created to reform regulatory procedures to make this arena more effective, responsive and participatory.<sup>12</sup> Under the auspices of what is referred to as “new governance,” efforts in Europe and Australia have been launched to revive regulatory law, particularly in the context of highly technical industries. New governance refers to a series of theoretical and applied approaches to regulation.<sup>13</sup> It carves out a middle ground between typical command and control models of oversight, on the one hand, and self-regulation, on the other. There is no single model of new governance; rather, there are a series of evolving models that have been developed and tried in various industries around the globe. The underlying point of new governance is that regulation, to be effective, must have greater flexibilities built into it, and those flexibilities ought to be driven by goals for outcomes and not processes. An example of new governance can be seen in US health care in the adoption of an industrial engineering process for Medicare deemed status, known as ISO 9001.<sup>14</sup> Contrary to the Joint Commission standards, ISO focuses on the use of quality procedures that are unique to a given institution’s needs, as opposed to a more rigid regulatory formula applied across the hospital care sector.

While a variety of models characterize new governance, two in particular have relevance to this essay, because they can be seen as templates underpinning an invigorated health planning process. The two models are

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11. See The Joint Commission, details found at <http://www.jointcommission.org>; National Committee on Quality Assurance, details found at <http://www.ncqa.org>.

12. Orly Lobel, *Setting the Agenda for New Governance Research*, 89 MINN. L. REV. 498 (2004).

13. *Id.*

14. Fierce Healthcare, *CMS Gives DNV Healthcare Authority to Accredite U.S. Hospitals* (Sept. 26, 2008). available at <http://www.fiercehealthcare.com/story/cms-gives-dnv-healthcare-authority-accredit-u-s-hospitals/2008-09-26>.

management-based regulation and responsive regulation.<sup>15</sup> Management-based regulation is oriented around planning and calls for regulated entities to develop their own unique solutions to particular problems. In the context of health planning, the state health plan can be viewed as a general template that lays out a vision for state and regional health planning. But how the general plan is invoked to foster broad goals such as service coordination, charity care, and public health can be tailored by regulated entities in unique ways that frame goals which are compatible and realistic, given individual institutional needs and capacities. In essence, management-based regulation would allow regulated entities considerable freedom in creatively meeting identified public health needs in a context very removed from the traditions of “one-size-fits-all” regulation.

Responsive regulation, on the other hand, while similar to management-based regulation, is perhaps more open-ended.<sup>16</sup> The state plan becomes a document that lays out a series of aspirations that regulators wish to see implemented in a respective jurisdiction. A responsive model concerns a process of self-evaluation in which an institution identifies its problems, guided by generic planning aspirations. Based on the self-evaluation, the regulated entities engage in a bottom-up process in which they evaluate particular problems, collect relevant supportive data, and craft unique, distinct solutions to given problem areas.

Neither management-based nor responsive regulation is totally open-ended, although initially may work with little or no guidance from the state, beyond the outlines of a broad planning document. But in both referenced models, the state actively oversees the activities of the regulated health institution and may even negotiate with a particular entity at the front end of the process to insure adoption of realistic compliance and meaningful goals.<sup>17</sup> The state would then continue to monitor the process through a system of reporting and evaluation. In addition, the state might need to use its broader powers to insure that institutional planning and problem solving be approached in ways that spill beyond institutional borders, becoming mechanisms for regional planning as well. To a large extent, state regulators take on the role of negotiator between regulators and regulated, but in cases of non-compliance retain their authority to invoke traditional regulatory oversight and sanctions.

No doubt some will argue that the past twenty-five years have demonstrated that state regulation is a hopeless quagmire, mired by politics

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15. John Blum, *A Revisionist Model of Hospital Licensure*, 2 REG. & GOVERNANCE 48-64 (2008).

16. J. Braithwaite, J. Healy, K. Dwan, *The Governance of Health Safety and Quality*, Commonwealth of Australia, 2005 (on file with author).

17. *Id.*

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and lack of resources. Health planning may be viewed as an idea that is at best arcane and, at worst, corrupt. In addition, the idea of altering the administrative process will be seen as an academic vision beyond the capacity of state bureaucrats who lack the creativity and power to rearrange the landscape of entrenched administrative law. Still, the current pathways of regulation characterized by layering and volumous complexities cannot be sustained. As influential as the federal government is in health regulation, the delivery system still exists at a local level, and, at this level, states are in a far better position to understand needs and idiosyncrasies of local public health. The current system that allows for health institutions to be independent actors with institutional interests spurred on by goals of market domination is inflationary and inefficient. The law is not cast in stone and merely is a vehicle to promote social policy. A broader vision of health is needed to create a more coherent health structure that is responsive to individual and collective needs, and effective planning and regulatory reform that reworks this old labyrinth are some steps that can move us toward a more rationalized, efficient delivery system.