

**NEW GOVERNANCE AND SOFT LAW IN HEALTH CARE REFORM**

**FINAL DRAFT**

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## **ABSTRACT**

A contemporary health care reform is underway, associated with a set of reformers who are active nationally and locally at the doctor/patient level, the health care institution level, and the policy level. This reformist energy is associated with processes in law and policy that can be called new governance and soft law. These processes are different from previous understandings of how health care can be governed, such as self-regulation, market forces, and new deal command and control regulation. These processes are taking hold and are visible in the public and private sectors and through out the health care industry. The paper discusses the relationship between resolving health care conundrums, such as universal access, eliminating racial and ethnic disparities and embedding information technology, and the new processes.

There are six innovations that derive from the interaction between new governance, soft law, and reform processes: alternative sites for deliberation, consumer and patient participation, different roles for government, redesigned organizational forms, and new tools for regulation and resolving disputes. Each of these innovations is discussed in the context of the health care reform stories. The paper discusses the variety of interactions between new governance and the older systems and how they coexist. It describes three ways in which the older processes are maintained, or could be maintained while utilizing the newer more effective processes. One type is the dynamic interaction between the old and new, a second is orchestrating a multi-pronged strategy that incorporates new governance techniques with more traditional incentives. The third interaction is the integration of traditional legal values, such as transparency, inclusion, and equity into the new processes.

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## **INTRODUCTION**

A different context in health care is emerging since the failure of the Clinton health plan and the routinization of managed care. The context displays new technologies, shifts in governmental roles, and available comparative quality and cost information. This context also includes: evidence based medicine that allows protocols that standardize care and correct variations in quality; the competitive global economy which requires cost effective health care for workers; and the fiscal crisis of state and federal government. However, the context also includes continued insecurity about health care coverage for employed workers and the uninsured, and increasing evidence of poor quality of care and inequities in health care treatment.

In the midst of this complex context highly visible health care reformers are evident. These reformers advocate that change is here, that these changes will be radical, and that these changes will work. They sense momentum and believe that the tipping point for transformation is in sight. These reformers are optimistic about resolving the continuing health care problems despite this complex context. The reformers are working to solve the ongoing health care conundrums. There are three stories that demonstrate the reform process. The first story is the longstanding challenge of universal access. The historical inability of the United States to use the international models for universal coverage is well documented. Over the last ten years an alternative incremental approach is underway. The alternative approach is based on state based experimentation combined with federal funding and multilevel interaction. The second story is about brand new technologies that challenge the former system. Information technology allows complex information to be communicated in a timely and flexible form to health care professionals. The technology for communication is coming at the same time as an explosion in the ability to produce evidence based treatment through protocols and standardization. The coming

together of digital information with evidence-based knowledge presents a great opportunity for improving quality of health care. However, the barriers of the existing system serve as an impediment to the embedding of new technologies. The third story is about reducing the health care inequities. The disparities among racial and ethnic minorities, in health care outcomes, are a longstanding scandal in American health care. However, with the ability to improve quality through technology innovations and evidence-based medicine, disparities in health care outcomes could be substantially reduced. This challenged the conventional belief that anti-discrimination tools are the primary method for eliminating disparities.

These stories show how the reformers are working to resolve these health care conundrums. As the stories are analyzed, they demonstrate a set of processes and understandings that are substantially at variance with previous views about the relationship between professionalism and expertise, and markets and government regulation. These new processes are facilitating the reformers' ability to solve health care problems. The new processes challenge the older beliefs of how governance can work to resolve health care problems. They also demonstrate a rethinking of how law can enable policy renovations.

The stories show the interaction between the problem to be resolved and the way governance and law is changing to resolve these problems. The three stories looked at together reveal a set of innovations that derive from an interaction between the new governance, new forms of law, and reform processes. These innovations can be seen as enabling a reformed health care system that is both efficient and equitable. One aspect of the innovations is that while they embody much of the new governance and soft law elements, they also contain aspects of the earlier self-regulation, command and control/entitlement, and market incentives that characterize the earlier periods. These innovations are works in progress with issues of participation in the processes, continuing inequities based on income and education, commitment to funding, and ensuring the publicness of the policies that are emerging. However, there is

evidence of varieties of coexistence between the new governance and the older systems that may give guidance into the potential benefits of the reforms to be both effective and legitimate.

The paper begins with a discussion of the contemporary health care reform that is underway. It describes the interest in health care reform that is moving to the top of the agenda because of global forces combined with internal dissatisfaction. This resurgent energy is associated with a set of reformers who are active nationally and locally at the doctor/patient level, the health care institution level, and the policy level. The paper describes the three health care conundrums that frame the reform efforts and reveal the methods that are utilized to resolve these conundrums. The paper then discusses the relationship between resolving these conundrums by contrasting traditional governance forms with the new mechanisms. The paper describes the relationship between these new mechanisms that might be called new governance and soft law. The paper then describes six innovations that derive from the interaction between new governance, soft law and reform processes: alternative sites, consumer and patient participation, different roles for government, redesigned organizational forms, and new tools for regulation and resolving disputes. Each of these innovations is discussed in the context of the health care reform stories. The paper concludes with a discussion of the variety of interactions between new governance and the older systems. It describes three ways in which the older processes are maintained, or could be maintained while utilizing the newer more effective processes. One type is the dynamic interaction between the old and new, a second is orchestrating a multi-pronged strategy that incorporates new governance techniques with more traditional incentives, and a third is integrating traditional legal values into the new processes.

## I. Health Care Reform: Three Stories

82% of Americans rank health care among their top concerns.<sup>1</sup> People are satisfied with health care when they can get it but are afraid they will not be able to secure it. Over 45 million people were without health insurance during 2003.<sup>2</sup> Inadequate health care quality has been well documented. Compounding the problems is an extremely complicated health care scheme. Health care coverage is provided through a mixed public, private, and nonprofit system. It delivers services through local provision with federally controlled programs such as Medicare and through varied benefits provided by employer-based plans.

These problems in health care must be tackled in a complex context. This context includes the availability of transformative technology that can radically change the way in which health care is delivered and accessed. It also includes an interest in shifting power to lower levels of government and the appreciation of more individual responsibility and involvement. The increasing speed of new medical research and knowledge, including information about improving care through community and public health measures, requires a more flexible and responsive system. The competitive world economy is also straining the employer based health care system. Since a large portion of health care is paid through employer payers it is inhibiting many firms from competing in this environment.<sup>3</sup> Rising costs are also a major issue straining the fiscal budgets at the state level, due to Medicaid, and at the federal level due to Medicare.

Like costs, liability is also a background driver. The medical malpractice method of deterring negligence and redressing patient harms is no longer efficient and equitable. Improved evidence based medicine combined with the collection and dissemination of data has two effects on malpractice. One, it

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<sup>1</sup> Paul Krugman, *The Health of Nations*, N.Y. TIMES, Feb. 17, 2004, at A23.

<sup>2</sup> U.S. Census Bureau, *Income, Poverty, and Health Insurance Coverage in the United States: 2003*, 14 (August 2004).

<sup>3</sup> Daniel Akst, *The Hidden Price Tag For Health Care*, N.Y. TIMES, Dec. 12, 2004, at BU6

increases the potential for liability because if medical providers have not installed the standards for good practice their mistakes are more easily revealed. On the other hand, the transparency of errors, and resulting exposure to malpractice, will drive providers to install quality compliance systems. As the system for preventing errors becomes effective it will result in the liability of the whole system, rather than the individual provider.<sup>4</sup>

Another aspect of the contemporary context is the recent failures of ambitious proposals to improve the health care system, such as the Clinton health plan and managed care. The Clinton health plan was an effort to achieve a seamless universal system through an elaborate, federally controlled, all-embracing system. The Clinton health plan was defeated in part because it was viewed as an attempt to replace the existing, diverse, and complex health care system with a mammoth bureaucracy. The failure is viewed as a vote against centralized, government dominated, bureaucratically controlled governance.<sup>5</sup> The experiment with managed care, represented as a managed competition approach to solving the health care problems, has also reached a plateau. It reached a plateau due to a perceived consumer desire for choice and the limits of its initial cost savings.

Nonetheless, Stakeholders realize that these problems can and must be tackled, even in this complex context. Tackling these problems is essential for the U.S. to have a strong, growing economy and provide excellent high-quality health care for all people. The stakeholder groups that are essential include physicians, health care providers, business, government, consumers/patients, and technology experts and entrepreneurs. A set of reformers is emerging from the stakeholders. These reformers range

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<sup>4</sup> William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387, 399 (2003). Medical disciplinary boards have also proved a mixed success as a way of preventing medical errors and of providing redress for patients. *See also* the effect on medical disciplinary boards, Ruth Horowitz, *Medical Licensing and Discipline in the United States: Medical, Legal and Public Discursive Domains* (June 2005) (unpublished manuscript, on file with author).

<sup>5</sup> Louise G. Trubek, *Health Care and Low-Wage Work in the United States: Linking Local Action for Expanded Coverage*, in *GOVERNING WORK AND WELFARE IN THE NEW ECONOMY* 292 (Jonathan Zeitlin and David M. Trubek, eds., 2003).

from former Secretary of Health and Human Services Tommy Thompson<sup>6</sup>, physicians such as Donald Berwick, health lawyers and educators such as Troy Brennan, and consumer leaders such as Ron Pollack. These reformists are leading in the emergence of new techniques and theories that challenge the older systems. These techniques and theories allow the reformers to figure out ways to improve health care within the contemporary context. These insights create energy for change among these reformers, despite the overwhelming problems in health care. There is an understanding among the reformist stakeholders that change is essential for the economic and personal health of the nation and that their actions are creating the basis for that change.

Converting the U.S. health care system to an excellent producer of high-quality care for a reasonable price is a daunting task. Health care reformers are working at transformation through tackling certain specific issues. There are three specific conundrums that are particularly important: how to achieve universal coverage, how to embed technology into health care delivery, and how to attain high quality care for all. A series of initiatives is emerging from people searching for new ways of resolving the ongoing problems. The new actors are participating in a series of collaborations and dialogues. Local, state, and federal governments are working with health care institutions at the policy level, as well as business and consumer groups. Health care institutions are working together to make changes, such as developing standardized data collection tools that will work within and across institutions. At the patient-provider level, the interaction is changing from a hierarchical relationship to that of sharing expertise.

### **Universal Coverage: From a centralized, single system to incrementalism**

The lack of universal coverage has long been the most noted deficiency in U.S. health care. The effects on the uninsured are notable in personal health, the additional costs to the health care system, and on the economic health of the nation. The lack of insurance in the U.S. results in poor health for those

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<sup>6</sup> Tommy G. Thompson, *Foreword: The State of America's Health Care System*, 31 WM. MITCHELL L. REV. 805 (2005).

residents who are uninsured. In addition, it results in the shifting of the costs for providing care of the uninsured onto two sets of payers: the employers, who pay more, due to the medical establishment shifting their added costs on to them, and the government payers, who are forced to raise taxes in order to cover their share of uncompensated care. It also affects the economy by encouraging job lock where employees cannot move to the position that matches their talents because of their fear of losing health care coverage.

There is now an acknowledged consensus that some form of universal coverage for residents is essential for the economic and personal health of the U.S.<sup>7</sup> This consensus has developed for two reasons: the acknowledgment by business that universal coverage is crucial for its success and a shift in vision to one based on an incremental approach. The incremental approach took off in the wake of the Clinton plan's failure.<sup>8</sup> The critics of the incremental approach assert that the abandonment of the rights/entitlement model can never achieve the universality that is essential for an effective and efficient healthcare system. They argue that the fiscal constraints of state government and the elimination of entitlements that are judicially reviewed will undercut the coverage and that low-income people will once again lose coverage. However, they admit that the political will for the single-payer, rights/entitlement route is gone.<sup>9</sup> The incremental approach reassures business and providers who fear a government controlled, one-size-fits-all model for health care. It de-emphasizes the bureaucratic, single set of universal benefits and administration. Business is getting involved to solve the problem of the uninsured because it sees that solving the uninsured problem is necessary for their own economic health and the

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<sup>7</sup> The business case for universal coverage is increasingly documented. See e.g., Paul Fronstin, *The "Business Case" for Investing in Employee Health: A Review of the Literature and Employer Self-Assessments*, EBRI Issue Brief No. 267 (March 2004).

<sup>8</sup> *Facing Health Care Tradeoffs: Costs, Risks and the Uninsured* La Follette Policy Report (Robert M. La Follette Sch. of Pub. Aff., University of Wisconsin-Madison), Winter 2003-04.

<sup>9</sup> David A. Super, *The Political Economy of Entitlement*, 104 COLUM. L. REV. 633 (2004). See also TIMOTHY STOLTZFUS JOST, *DISENTITLEMENT?: THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE* (2003).

competitive situation of the U.S. in the world economy. Business groups understand, to the extent they can no longer afford their own health care programs, other programs to cover their worker will have to be designed and paid for.<sup>10</sup>

The incremental approach to universal coverage is proceeding on four tracks: experimenting at the state level, integrating networks with federal funding, linking public and private coverage, and incorporating coverage for the uninsured through pooling and incentives. There is now a rich array of state approaches to providing coverage. In the 2005 budget debate, the National Governors Association united, across bi-partisan lines, to oppose massive cuts in Medicaid and develop a system for reforming Medicaid that cut costs while maintaining coverage and improving quality. The Medicaid cuts were reduced and a high level Medicaid commission is being appointed.<sup>11</sup> This commission's goal is to work with a variety of stakeholders including state and federal leaders to figure out ways that Medicaid funding can be more efficiently used to expand access and improve quality. The strength of the governors in the recent Medicaid debate is based on the state-by state incremental approach that has been ongoing for the past several years. State governments are experimenting with various methods trying to figure out ways of putting the pieces together to achieve greater coverage.<sup>12</sup>

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<sup>10</sup> In some cases like General Motors profits are falling. See Matt Miller, *CEOs Should Force Health Care Issue*, WIS. STATE JOURNAL, May 22, 2005. For Wal-Mart the issue is covering low wage workers. See Stacy Forster, *Big Companies Fill BadgerCare Rolls*, MILWAUKEE JOURNAL SENTINEL, May 24, 2005, at A1.

<sup>11</sup> *Lawmakers Express Anger Over Leavitt Medicaid Commission*, Washington Health Policy Week in Review (The Commonwealth Fund), May 23, 2005

<sup>12</sup> A recent study indicated that Medicaid care is equivalent to the access to low income privately insured adults. This information supports the usefulness of considering options for expanding Medicaid or expanding coverage for low income people through private plans, perhaps with a government subsidy. See, Teresa A. Coughlin et al., *Assessing Access to Care Under Medicaid: Evidence for the Nation and Thirteen States*, 24 HEALTH AFFAIRS 1074 (2005); *State Health Insurance: Making Affordable Coverage Available To All Americans*, FOSTERING RAPED ADVANCES IN HEALTH CARE (INSTITUTE OF MEDICINE), Nov. 2002, at 69.

Combining public programs with employer-based coverage is also being proposed through further expansion of Medicaid and encouraging small business to offer health care coverage through a combination of tax credits and subsidies from government programs. One approach that the Governors are endorsing is the development of multistate pharmaceutical purchasing pools for any person who does not have coverage to pay for pharmaceuticals.<sup>13</sup> An additional plan does pool pharmaceutical purchasing for Medicaid recipients, state employees, and other state public programs within the state.<sup>14</sup> The creation of large pools at the state level can also be used to reduce costs for business by including private businesses in these large state pools, which were exclusively for state employees.<sup>15</sup> In Wisconsin for example a proposed bi-partisan plan would require all employers to pay into a plan run by a new, private non-profit corporation. The proposal would include a health savings account and a tiered set of benefits.<sup>16</sup> A seamless system linking public and private programs requires horizontal networks within the states and communities to allow public programs and private employers to communicate and share information on eligibility. Information technology enables people to move from public plans to private coverage and vice versa with no loss of coverage when their job and income situation requires.<sup>17</sup> States are emphasizing quality techniques, patient involvement, and community participation to improve care.<sup>18</sup> Networks of state

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<sup>13</sup> Press Release, Illinois Office of the Governor, Gov. Blagojevich and Cong. Emanuel joined by Wisconsin Gov. Doyle in launching I-SaveRx prescription drug importation program; Citizens of IL and WI now able to purchase Rx drugs from Europe and Canada (Oct. 4, 2004), at <http://www.illinois.gov/PressReleases/PressReleasesListShow.cfm?RecNum=3439>. See also Gretchen Ruethling, *5 Drug-Importing States Add 2 Countries as Sources*, N.Y. TIMES, at A15.

<sup>14</sup> Press Release, Illinois Office of the Governor, Governor announces new Illinois Rx Buying Club promotional efforts during National Senior Citizens Month (May 2, 2004), at <http://www.illinois.gov/PressReleases/PressReleasesListShow.cfm?RecNum=3021>.

<sup>15</sup> David Callender, *Health Plan Would Cover All in State*, CAPITAL TIMES, June 15, 2005, at A1

<sup>16</sup> *Id.*

<sup>17</sup> *Facing Health Care Tradeoffs: Costs, Risks and the Uninsured*, La Follette Policy Report (Robert M. La Follette Sch. of Pub. Aff., University of Wisconsin-Madison), Winter 2003-04. See also *State Health Insurance: Making Affordable Coverage Available To All Americans*, FOSTERING RAPID ADVANCES IN HEALTH CARE (INSTITUTE OF MEDICINE), Nov. 2002, at 69.

<sup>18</sup> *Frist-Bingaman Bill Would Allow Uninsured Children to Enroll in Medicaid, SCHIP*, Washington Health Policy Week in Review (The Commonwealth Fund), May 23, 2005. The incremental approach is

government officials, legislators, and governors across states are spreading “best practices” and encouraging united action to support the programs.<sup>19</sup>

### **Embedding Technology: From command and control to national standards and regional collaboratives**

Reformers are pursuing major initiatives to embed technology in the health care system, which has been a notable laggard. There is a bi-partisan alliance between former Republican Speaker Newt Gingrich, Representative Patrick Kennedy and Senator Hillary Clinton aimed at overcoming resistances to the measures necessary to embed technology. The alliance reflects the continued reports<sup>20</sup> that describe how advanced technology could radically transform the quality and reduce the cost of healthcare. However, there is reluctance in the medical community to invest in technology stemming from high costs, a perceived loss of autonomy in using their professional expertise, and fear of a centralized data set.<sup>21</sup> There is also difficulty in developing a national inter-operable system that provides assurance that privacy and security are protected.<sup>22</sup> The Bush Administration has proposed a national healthcare regional infrastructure, which will be responsible for coordinating all private sector initiatives into the American Health Information Community.<sup>23</sup> The goal is to create a comprehensive knowledge-based network of interoperable systems capable of providing information anytime, anywhere. It is, however, not a central database of medical records. The role of the federal government is to ensure that standards are in place to

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based on states combining the resources of the Medicaid program as expanded through the State Children’s Health Insurance Program (SCHIP) funds. SCHIP is an expansion of health care coverage targeting uninsured children. The federal government, in enacting SCHIP, encouraged states to experiment with various approaches to insuring children and families with the additional funding.

<sup>19</sup> Louise G. Trubek, *Health Care and Low-Wage Work in the United States: Linking Local Action for Expanded Coverage*, in GOVERNING WORK AND WELFARE IN THE NEW ECONOMY 292 (Jonathan Zeitlin and David M. Trubek, eds., 2003).

<sup>20</sup> *Information and Communications Technology Infrastructure: A “Paperless” Health Care System*, FOSTERING RAPID ADVANCES IN HEALTH CARE (INSTITUTE OF MEDICINE), Nov. 2002, at 57.

<sup>21</sup> Newt Gingrich & Patrick Kennedy, *Operating in a Vacuum*, N.Y. TIMES, May 3, 2004, at A25.

<sup>22</sup> Press Release, Office of the National Coordinator for Health Information Technology, Questions and Answers American Health Information Community (June 6, 2005), at <http://www.hhs.gov/healthit/qa.html>.

<sup>23</sup> *Id.*

allow the interoperable systems; the model is the banking information infrastructure. The proposal funds local demonstration projects based on the concept that local governance facilitates the trust necessary to realign incentives. The proposal is for “regional” systems that could be smaller or larger than states; it is coordinated through the Connecting Communities for Better Health, a federally funded program.<sup>24</sup> The AHIC is a forum that includes 17 commissioners representing consumers, privacy interests, states, payers, providers, vendors, and purchasers.<sup>25</sup> The group is “chartered for two years, with the option to renew up to five years, to be succeeded by a private-sector health information community initiative.”<sup>26</sup> While the federal government is initiating this effort their investment is relatively modest. As the move towards proceeds there are various elements for the health care information and communication infrastructure. One of the ongoing debates is the relationship between the electronic health records, which are primarily considered to be in the domains of the providers, and the personal health records, which are in the control of the patient. There is also the importance of the access to the electronic medical record system for public health purposes. The interrelationship between these three dimensions is an ongoing aspect of the move to the embedding of electronic systems within health care.<sup>27</sup>

These current efforts build upon the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA delegated power to the Department of Health and Human Services (HHS) to promulgate rules to advance health care technology through uniform standards for electronic transactions, privacy protections and security of data. The production of the rules relied on the traditional federal

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<sup>24</sup> Website funded through an agreement with the Health Resources and Services Administrative Office for the Advancement of Telehealth, <http://telehealth.hrsa.gov/>.

<sup>25</sup> Press Release, Office of the National Coordinator for Health Information Technology, Questions and Answers American Health Information Community (June 6, 2005), at <http://www.hhs.gov/healthit/qa.html>.

<sup>26</sup> *Id.*

<sup>27</sup> William W. Stead et al., *Achievable Steps Toward Building a National Health Information Infrastructure in the United States*, 12 JAMIA113 (2005).

Administrative Procedure Act rule-making process and took many years and many hearings to finally produce pages of rules. The proponents of HIPAA relied on the command and control model. However, the rules-based system seemingly proposed in HIPAA was never quite the old model. The concept underlying the need for a standardized system across competing providers and insurers was initiated by a series of public-private collaborations, known as HIPAA Collaboratives. State-based and local collaboratives consist of all the stakeholders: business, government, technology experts, and providers from all types of backgrounds. Since HIPAA has been enacted, these groups have been helping their members comply with HIPAA by providing information and sharing techniques.<sup>28</sup>

### **Guaranteeing Quality and Equity: From anti-discrimination and medical malpractice to quality assurance tools**

The reformers realize that just having health insurance is not enough to guarantee health; the care must be high quality. Since the late 1990s, reformers from the medical sector and concerned business purchasers<sup>29</sup> have promoted quality as an achievable and necessary goal for the health care system. Although the U.S. has one of the most expensive health care systems in the world, the quality of care is mixed. The Agency for Healthcare Research and Quality's *National Healthcare Quality Report* indicates that the U.S. system currently does not do enough to prevent diseases, diagnose them early to improve treatment outcomes, or provide coordinated care to patients with chronic diseases.<sup>30</sup> In addition, uneven quality is particularly noticeable in connection to the disparities of health outcomes of racial and ethnic minorities. Studies have shown that minority Americans receive less health care and what they do receive tends to be lower quality care, even controlling for insurance status and income.<sup>31</sup>

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<sup>28</sup> Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives, What Can We Learn?*, 56 ADMIN. L. REV. 739 (2004).

<sup>29</sup> See Leapfrog, <http://www.leapfroggroup.org/>.

<sup>30</sup> *National Healthcare Quality Report*, AGENCY FOR HEALTHCARE RES. AND QUALITY at 2-4 (2003), available at [http://qualitytools.ahrq.gov/qualityreport/download\\_report.aspx](http://qualitytools.ahrq.gov/qualityreport/download_report.aspx).

<sup>31</sup> Sidney D. Watson, *Race, Ethnicity and Quality of Care: Inequalities and Incentives*, 27 AM. L. J. & MED. 203, 208-9 (2001).

In response to the documentation of the persistence of health disparities, there is a major initiative led by reformist health care leaders to adopt a quality-based approach to the provision of health care as an indirect route to achieving equality. A recent report called “Within Our Reach” indicates “leveraging existing quality assurance systems to monitor and address disparities could substantially reduce the disparities in healthcare treatment.”<sup>32</sup> If the problems with quality can be resolved, it opens the way not only to a high-quality health care system, but also a reduction in health disparities. Health care providers can more easily cope with the controversial subject of health disparities using the quality mantra. Once providers and payers are committed to the assessment and measuring of quality, they can use these techniques to access and improve the outcomes for racial and ethnic minorities. There is evidence that publication of quality indicators can be effective to improve quality for minority populations. A recent study demonstrated that the quality of care improved for minority populations when public data on the success of physicians were made available and distributed to minorities.<sup>33</sup>

## II. New Governance and Soft Law

In health care, there is a historical mix of self-regulation, market forces, and government regulation.<sup>34</sup> The health care reforms just described represent a significant change in governance. Rand Rosenblatt defines this mix as the remains of the three ages of health law: authority of the medical

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<sup>32</sup> Kevin Fiscella, *Within Our Reach: Equality in Health Care Quality*, Symposium, Racial and Ethnic Disparities in Health Care Treatment, The Harvard Civil Rights Project (May 18, 2004) (unpublished manuscript, on file with author).

<sup>33</sup> Dana B. Mukamel et al., *Quality Report Cards, Selection of Cardiac Surgeons, and Racial Disparities: A Study of the Publication of the New York State Cardiac Surgery Reports*, 4 *INQUIRY* 435 (2004-2005).

<sup>34</sup> Troyen A. Brennan, *The Role of Regulation in Quality Improvement*, 76 *THE MILBANK QUARTERLY* 709 (1998). The argument is that in no substantive area was there ever true self-regulation because there was always some government action in some way, be it administrative, legislative, or judicial.

profession, modestly equalitarian social contract and market competition.<sup>35</sup> The authoritative period of the medical profession was characterized by self-regulation and accreditation as the preferred ways to govern. The second age that Rosenblatt defines as “modest social contract” is sometimes called the “new deal/great society period.”<sup>36</sup> This governance system emphasized command and control based in Washington DC. The administrative agencies issued periodic rules and emphasized professional expertise as the source of information and knowledge. There was an emphasis on entitlement programs and a reliance on individual litigation.<sup>37</sup>

Since the 1970s, critics of government regulation and the administrative state have called for alternatives to the new deal/great society model. Rand Rosenblatt defined the period that comprised privatization, deregulation and reliance on market competition as the third age.<sup>38</sup> Managed care is one manifestation of that period. While managed care succeeded in reducing costs, briefly, it engendered a backlash from physicians and consumers. The widely used phrase was that it “managed costs not care.” The inability of these tools, and institutions to resolve health care problems is highlighted in the failure of the Clinton health plan. Rosenblatt describes “President Clinton’s attempt to solve these problems with a national health insurance proposal that ingeniously combined the social contract, market competition and professional authority models, but was unable to mobilize the political support to overcome intense opposition.”<sup>39</sup>

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<sup>35</sup> Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155 (2004).

<sup>36</sup> Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004).

<sup>37</sup> For an extensive discussion of these issues see, William H. Simon, *Solving Problems v. Claiming Rights: The Pragmatist Challenge to Liberal Legalism*, 46 WM. & MARY L. REV. 127 (2004). In health care medical malpractice is used to redress negligent errors and civil rights litigation is used to redress discriminatory behavior were the tools employed.

<sup>38</sup> Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155 (2004).

<sup>39</sup> *Id.* at 175.

The health reform stories describe an emerging set of practices that can be called “new governance” or “post-regulatory”, or “new proceduralism.”<sup>40</sup> The appearance of new governance techniques in health care is an important aspect of the way in which reform is developing as described in these stories. These new governance techniques are intertwined with the reinvisioning of how to improve health care. In a recent article one observer posited that these practices can be called a fourth age of health law.

This fourth age is linked to a more general shift in how governance is evolving. While this paper describes new governance in health care, other sectors also demonstrate these emerging practices. New governance is a broader phenomenon and its aspects are shared in these different sectors ranging from work place safety programming to the environment.<sup>41</sup> The word new does not imply that it has been invented recently; rather it is used to refer to widespread and explicit use of nonconventional forms of governing.<sup>42</sup> New governance is not about privatization—it is post privatization. It is redefining relationships among government, markets, and individuals. It is not about spending less money but spending it better. It is not even about less paperwork or less regulation. New governance is a third way between traditional administrative law and total deregulation. It is about effectiveness and equity. It restructures relationships among markets, government, professional expertise, and re-opens the age-old issue of how best to maintain social and environmental values in a market economy. It recognizes that,

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<sup>40</sup> Scott L. Cummings, Political Mobilization in the Post-Regulatory State: Cause Lawyering and the Community Economic Development movement, Paper Presented at the Lawyers and Social Movements Conference (Mar. 4, 2005) (on file with author) (post-regulatory); Wolf Heydebrand, Hard but Soft: Having Law Both Ways? (March 2005) (unpublished manuscript, on file with author) (new proceduralism); Lester M. Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 FORDHAM URB. L. J. 1611, 1635 (2001) (new governance).

<sup>41</sup> See Orly Lobel, Interlocking Regulatory and Industrial Relations: The Governance of Workplace Safety (Oct. 20, 2004) (forthcoming in *Administrative Law Review* 2005) (OSHA); Bradley C. Karkinnen, Environmental Lawyering in the Age of Collaboration, 2002 Wis. L. Rev. 555 (2002) (environmental).

<sup>42</sup> Task Force on Legal Issues II, New Modes of Governance in Europe (NEWGO) May 16, 2005 (Grainna De Burca ed.), [http://www.eu-newgov.org/datalists/deliverables-detail.asp?Project\\_ID=26](http://www.eu-newgov.org/datalists/deliverables-detail.asp?Project_ID=26).

while privatization can bring important new tools to help solve problems (like market-based approaches), “private markets cannot be relied on to give appropriate weight to public interests over private ones without active public involvement.”<sup>43</sup>

New governance includes devolution, public-private partnerships, new types of regulations and incentives, network creation, coordinated data collection and dissemination, benchmarking, monitoring, and active individual involvement.<sup>44</sup> Devolution means moving power to lower levels of government, including local and state with less emphasis on nationally administered programs with little flexibility. There is multilevel interaction where the national government sets standards, or provides funding with a back and forth relationship between the federal, state and local level. The idea of experimentation is closely linked to devolution, since the more local an entity is, the easier experimentation becomes. Often, experimentation occurs outside the realm of regulation or parallel to it.<sup>45</sup> Experimentation can also be seen as similar to continuous quality improvement —organizations should be constantly experimenting to see what works and what does not.<sup>46</sup> There is experimentation with different models of resolving problems at the state and local level. This experimentation is producing information about what works and doesn’t work and this information is shared through shareholder networks, such as networks of government officials and business purchasers. Devolution does not mean there is no role for coordinating institutions and systems. The local groups, which provide diversity, require some form of orchestration, either through horizontal sharing or through multi-level feedback. The larger entity takes the information and experience and distributes it to other like programs. Orchestration is also necessary to ensure that the

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<sup>43</sup> Lester M. Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 *FORDHAM URB. L. J.* 1611, 1635 (2001).

<sup>44</sup> Salaman and Lobel(renew deal)

<sup>45</sup> Louise G. Trubek, *Lawyering for a New Democracy: Public Interest Lawyers and New Governance: Advocating for Health Care*, 2002 *WIS. L. REV.* 575, 594 (2002).

<sup>46</sup> *Id.* at 587.

quality of the services provided at the local level is adequate and to prevent a race to the bottom that occurs with isolated and fragmented local projects.

Another element is public private partnerships where traditionally isolated organizations and programs are brought together to work on shared problems, crossing the traditional barriers of diverse corporate forms and competing constituencies. The knowledge that is employed to work on these problems is expanded to include users and local context as well as techniques such as information technology. It is also closely linked to networking: a process of finding out from organizations in the field what already works or does not work and adapting to this information. The use of networks also changes the role of government because it no longer regulates or commands organizations to achieve desired outcomes. While negotiation through networks may be difficult, rules and standards that have been negotiated by the networks may be better complied with because of the negotiation process.<sup>47</sup> Traditional governance has been skeptical of collaborations between private and public entities. New governance recognizes that public/private networks have different strengths that can be used in concert to solve public problems.<sup>48</sup> Economic incentives are used as part of the regulatory framework. There is emphasis on collecting data in order to evaluate whether goals, that are set and benchmarked, are achieved. There is emphasis on monitoring results through the collection and public dissemination of data that can lead to iteration and revisions. It can also be used as a basis to create economic incentives for providers by tying the payment to value.<sup>49</sup>

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<sup>47</sup> Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives, What Can We Learn?*, 56 ADMIN. L. REV. 739 (2004).

<sup>48</sup> *Id.* at 1633-34.

<sup>49</sup> One observer has said health care reform is all about purchasing for value. Dave Riemer, Commentary by Dave Riemer at University of Wisconsin Medical School, April 4, 2005 (comments on file with author).

An analysis of new governance tools and mechanisms reveals a contrasting view of law as it is traditionally understood.<sup>50</sup> New governance is transformative of law in that it challenges what we think of as law. Guidelines, benchmarks and standards that have no formal sanctions are important elements in new governance. There is also a development of informal processes to resolve grievances and disputes, including negotiation and multistep procedures.<sup>51</sup> This can be called soft law. Soft law is an important component of new governance practices.<sup>52</sup> One reason that the new governance practices are attractive is the inadequacy of traditional regulation and court-based dispute resolution. Hard law can be characterized as command and control, court based dispute resolution, uniform rules, punitive sanctions, and court challenges for noncompliance. This hard law approach has proved inadequate in many cases. First, the use of court challenges to enforce regulations has been ineffective due to the complexity of the problems seeking to be solved, the lack of fit between the institutional structures that are causing the failures with the remedies provided by courts, and the recent unwillingness of judges to undertake massive reforms through court systems.<sup>53</sup> The failure of the anti-discrimination paradigm in racial and ethnic disparities is an example. Another failure of traditional regulation is the use of malpractice litigation as the major tool to prevent errors and improve quality. The randomness of the cases, the high cost of litigation, including lawyers' fees, and the resistance of health care institutions to utilize the information about failures are all problems with the hard law approach. Finally, there is a famed gap between the law on the books and the law in action. Uniform rules are not automatically enforced by the

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<sup>50</sup> Task Force on Legal Issues II, *New Modes of Governance in Europe (NEWGO)* May 16, 2005 (Grainna De Burca ed.), [http://www.eu-newgov.org/datalists/deliverables-detail.asp?Project\\_ID=26](http://www.eu-newgov.org/datalists/deliverables-detail.asp?Project_ID=26).

<sup>51</sup> Alexander J.S. Colvin, *From Supreme Court to Shopfloor: Mandatory Arbitration and the Reconfiguration of Workplace Dispute Resolution*, 13 CORNELL J.L. & PUB POL'Y 581 (2004). Susan Sturm, *Second Generation Employment Discrimination: A Structural Approach*, 101 COLUM. L. REV. 458 (2001). Nan D. Hunter, *Managed Process, Due Process: Structures of Accountability in Health Care*, at <http://ssrn.com/abstract+630482>.

<sup>52</sup> David M. Trubek and Louise G. Trubek, *Hard and Soft Law in the Construction of Social Europe: The Role of the Open Method of Coordination*, EUR. L. J. 2005.

<sup>53</sup> Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. REV. 1015 (2004).

agencies, nor does enforcement necessarily lead to the desired outcome.<sup>54</sup> The perceived inability of the HIPAA rules to advance the consumer's interest in health data collection is an example of the gap between law on the books and effective achievement of the goal.

Soft law allows learning, feedback, non-blaming, encourages multidisciplinary approaches, and allows government to behave in a different way. It similarly allows other actors to take multiple roles and allows alliances between traditional adversaries. It also allows economic incentives to be incorporated into the governance framework while allowing for diversity and experimentation. It allows different domains, such as public and private agencies, and different regulatory clients, such as public health and health organization and financing, to interact more easily. "It can encourage mutual cooperation and exchanges of knowledge and experience through collection, systematization, and diffusion of knowledge. Soft law can be seen as fostering consensus making and incentives to voluntary learning, as much as by shaming."<sup>55</sup>

This discussion shows how new governance is transformative of traditional law. However, in assessing new governance it is important to evaluate how these techniques maintain traditional legal values of inclusion, equity, and participation and transparency. This assessment can be described as the coexistence of new governance and traditional law.<sup>56</sup> The larger issue is whether this evolving system can be both popular and effective. The partial failure of managed care and demise of the Clinton health plan was due to the inability of the reformers to demonstrate that people would be better off and fairly treated under that governance system. In envisioning this fourth age, it is important to maintain the positive aspects of the earlier ages, such as a social contract, trust in physicians, and the incentives of market.

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<sup>54</sup> David M. Trubek and Louise G. Trubek, *Hard and Soft Law in the Construction of Social Europe: The Role of the Open Method of Coordination*, EUR. L. J. 2005

<sup>55</sup> Kerstin Jacobsson, *Between Deliberation and Discipline: Soft Governance in EU Employment Policy* (unpublished document on file with author).

<sup>56</sup> David M. Trubek & Louise G. Trubek. *The Coexistence of New Governance and Legal Regulation: Complementarity or Rivalry?*, July 2005 (unpublished paper on file with author).

Skeptics of new governance believe that the issues of transparency, fragmentation, unproven success of new tools, and imbalance of power are major obstacles to the promise of new governance.<sup>57</sup>

The health care stories demonstrate that in this set of innovations there is an emerging set of soft law elements that are crucial for new governance. These innovations also include elements of more traditional legal processes and values. Section three describes these innovations. Section four indicates how these innovations demonstrate the coexistence of new governance and soft law with the traditional legal processes and values.

### **III. Innovations**

The older system without some changes cannot deal with the current problems of diversity, new technologies, increasing flow of new knowledge, and the eroding faith in professionalism. The old system cannot deal with the increased information that is now available through the combination of evidence based medicine at the same time as paper records move to electronic. This has created an explosion for the possibility of new knowledge. This new knowledge depends on feedback and iteration as the new information is obtained. This feedback requires interaction between domains, for example the information obtained from the public and private payer must be integrated at the policy and clinical level for the whole picture to emerge. It also allows for traditional public health to be merged with health care delivery, for example a physician with ten diabetes patients using the same protocols for treatment can obtain important information about diabetes treatments that can be shared internally as well as with other institutions. The use of benchmarking will lead to increased learning. As you improve benchmarking you learn about additional ways to do a better job. Initially there may be ten benchmarks, but over time the possibilities will multiply. The older system must be changed to reorient to a new productive system.

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<sup>57</sup> MARK TUSHNET, *THE NEW CONSTITUTIONAL ORDER* (2003). Tushnet has characterized the conservatives as having a vision and agenda that is persuasive and may be implemented. He sees the new governance vision as one of the few efforts to create a liberal counterpoint to the conservative vision.

The combination of linking information technology with evidence based medicine, new roles for the actors, and aligning incentives can lead to path redesign and path innovation.<sup>58</sup>

The innovations that are being created to accomplish these goals are the key elements of new governance in health care. The first is alternative sites that create stakeholder locations for interaction and implementation of programs and projects. The second innovation is the enhanced role of consumer/patient participation. Part of the inability of the older systems to adapt to the current context is the difficulty of figuring out how to integrate the essential knowledge of patients/consumers into the decision-making. The role of government changes becoming more of a set of functions that can be employed differently depending on the specific problem to be resolved. The role of private organizations shifts as well. The traditional distinction between public and private law becomes less effective as the government allows more economic and market incentives to play a role and as private corporations take on a more social function. While the innovations often result in larger units, such as public/private pooling, it also encourages development of smaller units, such as local clinics that can deliver care specific for the cultural and geographical needs of the community. Similarly, the traditional court based dispute resolution systems may be ill-suited for some of the revisability and learning aspects of new governance. However, redress for the individual is essential for the legitimacy of the processes. Dispute resolution systems that use “alternative forms of victim compensation through administrative processes similar to workers compensation and conflict avoidance through informal methods to explain and apologize for error.”<sup>59</sup> Finally, the new governance system uses information as a regulatory technique through the publication of data on physician’s results, fiscal incentives for good performance by hospitals and clinics, and government rules that allow diverse ways of achieving positive outcomes.

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<sup>58</sup> Barry P. Chaiken, Address at the Digital Healthcare Conference (June 9, 2005) (presentation on file with author).

<sup>59</sup> David M. Trubek & Louise G. Trubek, *The Coexistence of New Governance and Legal Regulation: Complementarity or Rivalry*, July 2005(unpublished document of file with author).

## A. Alternative Sites for Deliberation and Implementation

The failures of the late 1980s and the 1990s emboldened key stakeholders to overcome traditional animosities and self-interests and design new locations for experimentation in providing and paying for health care. The traditional arenas that brought together actors to debate, deliberate, and resolve problems were the administrative agency rulemaking process, the courts, markets, and self-regulation. However, none of these things seemed to work because: there were missing stakeholders, locations were inflexible, experimentation and diversity were difficult to achieve, enforcement relied heavily on sanctioning and the available new technology could not be integrated into the existing systems.

Reformers are creating new sites that encourage the collaboration that had been previously difficult to achieve. The most common sites are collaboratives that consist of a variety of stakeholders that convene to solve health care conundrums. Examples of these new sites are quality collaboratives, local technology groups, and groups planning to pool public and private coverage systems.<sup>60</sup> These collaboratives are at the local level, statewide and there are national groups such as the National Committee for Quality Assurance and the National Quality Forum.<sup>61</sup> The collaboratives allow for networking and rapid changes. The founders of the collaboratives realize that bringing varied expertise and broad experiences to the collective governance structure is essential.<sup>62</sup> Participating at these sites are the health care actors—providers, consumers, government, and employers, although the role for consumers in many of these collaboratives is lacking.<sup>63</sup> Each actor has important information that, when shared with all stakeholders, improves the understanding of and the ability to address a problem.<sup>64</sup> These

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<sup>60</sup> See discussion of proposals of David Cutler. Roger Lowenstein, *The Quality Cure?*, N.Y. Times Magazine March 13, 2005, at 46. See Dave Riemer's ideas on state pooling. Add news article

<sup>61</sup> See Wisconsin Quality Collaboratives, [www.wiqualitycollaborative.org](http://www.wiqualitycollaborative.org).

<sup>62</sup> Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004).

<sup>63</sup> See Wisconsin Quality Collaboratives, [www.wiqualitycollaborative.org](http://www.wiqualitycollaborative.org).

<sup>64</sup> Wendy Netter Epstein, *Bottoms Up: A Toast to the Success of Health Care Collaboratives, What Can We Learn?*, 56 ADMIN. L. REV. 739 (2004).

new collaborations may decide to bring in more organizations or have local pilot projects to see what works. This exploration leads to something different and perhaps more ambitious than what they started out with.

Four sets of reformers are now emerging as proponents and leaders of alternative approaches to solve the health care conundrums through these new collaborations: the pioneering physician, the concerned payor, the active consumer, and the facilitating government leader.<sup>65</sup> Each reformer participates in various networks, alliances, and forums in order to solve health policy problems. Each participant has a constituency that must accept working with the new alliances. These leaders must also change the culture of their constituency so the entire group accepts the value of collaboration and views it as a way to achieve their own goals.

The role of physicians is crucial in order for new governance in health care to be successful. Historically, professionalism was a way for physicians to mediate between the tensions of a market-driven approach to health care and the alternative of government regulation. Professional values and institutions have been viewed as necessary in order for physicians to maintain an independent role between the market and regulation. This worked successfully for physicians for a period of time. However, business and consumer advocates complained that physician control was resulting in higher costs, lack of access, and inconsistent quality of care. The managed care revolution in the 1980s, businesses' attempt to create a competitive market, drastically undermined these traditional professional institutions and controls and damaged physicians overall leadership. The recent backlash against managed care, created in part by the actions of health care providers, has emboldened them to once again assert their leadership role. The managed care backlash came about in part by an alliance, between physicians and consumers, to fight the intrusion of the "outsiders" into the physician-patient relationship. Although physicians won this battle,

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<sup>65</sup> Thomas R. Oliver, *Policy Entrepreneurship in the Social Transformation of American Medicine: The Rise of Managed Care and Managed Competition*, 29 J. HEALTH POL. POL'Y & L. (2004). These actors have the characteristics of the "policy entrepreneur," crucial to the implementation of these new routes

managed care had changed the environment in which they practice through the development of large integrated hospital and clinic systems where most physicians now practice, the creation of evidence-based medicine, and increased reliance on allied health care professionals. As one observer noted, "... physicians are weakened but not vanquished."<sup>66</sup> In attempting to reassert their leadership role, physicians noted the effectiveness of business leaders in advancing quality in health care through the use of networks. They now emulate these network collaborations by working with a wide variety of stakeholders.

Although physicians are asserting a new role, the concerned employer-payer, who emerged in the 1980s to control health care costs, is still active and prominent. Since provision of health care coverage in the United States is significantly through the workplace, employers wanted to control health care costs because they are a major factor in their profitability and sustainability. The pressures of the global economy require businesses to engage in global arenas that are not integrated into traditional sites. National competitiveness is being threatened by health care costs. Some large companies can no longer pay for health care for their workers through their revenues. Entrepreneurial companies cannot pay for health care as they "start up." This is why business leaders have joined the consensus for universal coverage. Alternative sites may encourage business reformers to launch the effort for universal coverage. In addition to the access problem, employers have expanded their activities to improving quality and even becoming active in solving the problem of the uninsured.<sup>67</sup> The leading voice of business in health care is the Leapfrog Group, a consortium of more than 100 large employers that have mobilized to use their purchasing power to affect the health care system. The Leapfrog Group, while national, has substantial influence on business actions at the state and local level. It exerts a major external force on the internal

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<sup>66</sup> Jill Quadagno, *Physician Sovereignty and the Purchasers' Revolt*, 29 J. HEALTH POL. POL'Y & L. 815 (2004).

<sup>67</sup> Milt Freudenheim, *Companies Band Together as a Way to Offer Health Care to Part-Time Employees*, N.Y. TIMES, at C3.

workings of health care institutions and professional groups through the production and dissemination of benchmarks on the quality and cost of health care procedures.<sup>68</sup>

These evolving collaborations, while often effective, face challenges. First, there are internal and external mechanisms that have to be refined in order for the process to achieve its goal. There is also a reliance on regionalism, a level of government that has been of mixed success in the United States. Finally, the “publicness” of these collaboratives is often insufficient.

There are internal mechanisms that affect the potential success of these collaboratives.<sup>69</sup> The first is the internal interests of the stakeholder. For instance, physicians are not a monolithic group. Surgeons, and pediatricians may be threatened by some quality standards in different ways.<sup>70</sup> Small businesses have different interests and power than the Fortune 500 companies. And the success of the collaborative may depend on who within the organization is participating and their relationship to their constituency. For example, the participation of the head of a stakeholder organization may provide certain kinds of authority, but if the head of the organization can’t sell the collaboration to the rest of the organization the goals of the collaborative may be undermined. These collaboratives contain internal costs that must be weighed against the benefits. These costs include the time of the stakeholders invested in lengthy meetings and interactions. The costs also include the dollars required to maintain an ongoing organization and to pay for staff. Finally, the process may be slow limiting flexibility, which is the *raison d’être* of such collaboratives.<sup>71</sup>

The external mechanisms that affect the success of the collaboration are the transparency of collaboratives, dampening of potential innovation by fears of liability and existing inflexible regulations,

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<sup>68</sup> See Leapfrog, <http://www.leapfroggroup.org/>.

<sup>69</sup> John Braithwaite, et al., *The Governance of Health Safety and Quality*, 27, fig.3 (2004) (manuscript on file with author).

<sup>70</sup> Rachell Callcut, *The Influence of Private Regulation on the Practice of General Surgery* (Dec. 6, 2004) (unpublished manuscript, on file with author).

<sup>71</sup> A. Bryce Hoflund, *An Exploration of the Costs Associated with Consensus Making in Healthcare: A Case Study of the National Quality Forum* (June 2005) (unpublished manuscript, on file with author).

and the absence of unorganized constituencies. State and federal administrative procedure acts and open records and open meetings laws do not apply to many of these collaboratives because they are not organized as public bodies. This makes the availability of information about their activities difficult to find and makes their work seem suspicious. One example to the contrary is the newly created American Health Information Community (AHIC), which provides a collaborative to accelerate the application of health information technology. The collaborative developed by the Department of Health and Human Services is specifically organized under the framework of the Federal Advisory Committee Act in order to allow for open public meetings and “widespread stakeholder participation in which everyone has a voice.”<sup>72</sup> In addition, fears of litigation based on malpractice may also be an obstacle to the development and implementation of innovative techniques. Substantive government regulations that do not allow for innovative systems, such as payment for quality, are also external checks on the effectiveness of collaborations. A third external barrier is the difficulty of participation by patients and consumers who have traditionally had difficulty organizing due to their diverse income, race, ethnicity, gender, and geography.<sup>73</sup>

Regional groups are also mooted. In President Bush’s proposals for disseminating new technology in health care<sup>74</sup> and in the Medicare Modernization Act,<sup>75</sup> there is a commitment to regionalism, described as below the Washington level but not necessarily at the state level. This is consistent with the academic discussion about “new regionalism” and “new localism.”<sup>76</sup> Scholars note that in order to achieve the

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<sup>72</sup> Press Release, Office of the National Coordinator for Health Information Technology, Questions and Answers American Health Information Community (June 6, 2005), at <http://www.hhs.gov/healthit/qa.html>.

<sup>73</sup> John Harley Warner, *Grand Narrative and its Discontents: Medical History and the Social Transformation of American Medicine*, J. HEALTH POL. POL’Y & L. 757, 769 (2004).

<sup>74</sup> Press Release, Office of the National Coordinator for Health Information Technology, Questions and Answers American Health Information Community (June 6, 2005), at <http://www.hhs.gov/healthit/qa.html>.

<sup>75</sup> See Medicare Modernization Update, <http://www.cms.hhs.govmmu/>.

<sup>76</sup> David J. Barron, *A Localist Critique of the New Federalism*, 51 DUKE L. J. 377 (2001).

values of local autonomy there needs to be a legal regime that encourages local participation; limiting centralized power is not enough to create greater diversity and participation. Some of the proposals now available cross states but are not geographically contiguous. Prescription drug pools for example now cross state lines. One example is the I-Save Rx plan where five states, that are not contiguous, are developing a shared pool to purchase drugs for a lower cost.<sup>77</sup> The states locations range from the Midwest to the East. The efficiency of this type of pooling comes from the ability to use one purchasing system to buy in bulk internationally and deliver the drugs via mail.

One striking aspect of the collaboratives is the interaction of public and private law that can be seen in the emerging public/private partnerships. These collaboratives have various organizational forms that allow them to have flexibility that can come from private interactions. What is needed is that all of these sites have some form of “publicness.” Getting public and private interaction is not easy because efficiency and legitimacy are both needed. One obstacle to getting the interaction right is the lack of coordination between public law and private law. Public law is embodied in administrative law and procedure. Private law is contract, tort and property. Each domain has a separate robust history, expertise, and skills. However, if these emerging private partnerships are to work they must be composed of aspects of both. One model would be through contract where the contract is with a public agency and where the services provided are subject to open meetings and open records requirements.<sup>78</sup> Another technique would be the monitoring of standards for these alternative sites by a credible organization.<sup>79</sup> It is probably best to have a period of experimentation for various models of “publicness” accomplished through sharing

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<sup>77</sup> Press Release, Illinois Office of the Governor, Gov. Blagojevich and Cong. Emanuel joined by Wisconsin Gov. Doyle in launching I-SaveRx prescription drug importation program; Citizens of IL and WI now able to purchase Rx drugs from Europe and Canada (Oct. 4, 2004), at <http://www.illinois.gov/PressReleases/PressReleasesListShow.cfm?RecNum=3439>.

<sup>78</sup> One example is the contract between the Wisconsin Department of Health and Family Services and the Wisconsin Hospital Association to administer the data collection program for the state.

<sup>79</sup> One example of this the work of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). See Blum, *supra* note

models designed to exchange experiences and evaluated for effectiveness.<sup>80</sup> The debate over the ownership of health data between the providers and the consumers is one example where various models are proposed. The second issue is who controls the availability and use of the data.<sup>81</sup>

## **B. Consumer and Patient Participation**

One distinctive feature of new governance practices is the increasing and changing role of the patient and consumer. The patient and consumer are envisioned as independent actors who can influence outcomes at the clinical and policy level. The development of economic incentives such as co-pays and positive economic incentives are methods of the individual using their market power to improve quality of health care. There is also the use of public information based on data that enable the consumer to make choices that will both improve the quality of their care and the entire system. These economic and information incentives can also be combined with methods of delivery that encourage the patient to participate in the management of their own care, particularly with connection to chronic illnesses. There is also a emphasis on consumer participation in the collaborative sites. Since the consumers are considered essential to the functioning health care improvement processes, the voice of consumers and patients is essential for the deliberations. The voices of the consumers and patients can be provided through groups of consumer, such as disease groups, and lawyers who represent disadvantaged groups, including racial and ethnic minorities.

In earlier periods the physician was relied on as the trusted agent for the patient since the physician was the source of knowledge. Physicians were also the major reformers of the health care

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<sup>80</sup> Cary Coglianese in his article *The Internet and Citizen Participation in Rulemaking from I/S* A Journal of Law and Policy for the Information Society discusses the tension between collaboration between regulators and industry and transparency of interactions. He points out that sometimes the public interest is advanced through informal communications that are not always visible to all.

<sup>81</sup> One commentator has noted that if these decisions on ownership and availability are allowed to be proprietary democratic values will be lost and our society could be called a “banana republic.” John Chapin, *Health Data in a Banana Republic* (Jan. 2005) (unpublished document).

system during the early 20<sup>th</sup> century.<sup>82</sup> During the great society period, consumers and patients participated in deliberation through public interest lawyer advocacy at the administrative agency, social movements at the legislative level, collective bargaining with employers, and litigation against discrimination and malpractice.<sup>83</sup> In the market model that emerged in the 1990s the consumers were sometimes viewed as creating costs unrelated to necessary care and were encouraged to join managed care organizations where the decisions on the type and quantity of care were made by management.

The rise of consumers as key players in health care is related to both the use of markets in health care as one tool of controlling costs, and the rise in chronic diseases that must be controlled by the patient's own involvement. Another aspect of the role of the patient is the increasing role of consumer driven purchasing, particularly health savings accounts.<sup>84</sup> Therefore, two consumer roles are important in health care: the role of the purchaser of healthcare services and that of the patient active in their own health care. After managed care, employer purchasers realize that more allies are needed to develop and implement any new healthcare system design. They view a strong consumer role as essential to any sustainable changes to the system. They also believe that giving consumers a greater voice in the purchase and delivery of health care is essential to creating a cost-effective and high quality system. The interface of the longstanding patient rights vision with the newer patient empowerment movement opened the path to a more active role for patients/consumers in the level of clinical and institutional decision making.<sup>85</sup> The initial move toward public disclosure, while led by business groups, now has the strong endorsement of traditional consumer groups such as Consumers Union. Consumers Union has created a campaign called "Stop Hospital Infection" to "...help consumers get the best quality of care by promoting

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<sup>82</sup> Joe Rees, *The Origins of Self-Regulation in the American Hospital Industry* (June 2003) (unpublished manuscript, on file with the author).

<sup>83</sup> Trubek, *supra* note 22.

<sup>84</sup> Barry Kozak, *New Health Savings Accounts Promote Consumer Driven Health Care*, 18 CBA RECORD 58 (2004).

<sup>85</sup> Sydney Halpern, *Medical Authority and the Culture of Rights*, 29 J. HEALTH POL. POL'Y & L. 835 (2004).

public disclosure of hospital infection rates...Consumers and employers can select the safest hospitals and competition among the hospitals will quickly force the worst to improve.” Consumers Union is endorsing the passage of legislation to require the infection rates be made public.<sup>86</sup> The emphasis on patient self-management has decentered the physicians and lawyers.

The new governance legal forms also require a revised role for lawyers. The new governance processes incorporate all the stakeholders in order to develop a system that acknowledges and utilizes diverse knowledge. Lawyers therefore can participate by representing their constituency and by developing processes and programs that work to improve the system. One example of a different role for lawyers is the quality approach to reducing disparities. The civil rights litigation approach embodied in the Title VI and HHS enforcement model were based on the lawyer as the adversarial advocate for the patient. In the quality assurance approach, the lawyer’s role would no longer be as an advocate for the individual or institutions alleging discrimination by health care providers and payers. It would decenter the court as the main arena for redressing the harm that came from discriminatory conduct. The major emphasis is placed rather on reforming internal health care systems through a combination of creating incentives for positive outcomes and evidence-based medicine. Employees and government payers would tie payment to quality outcomes, including compliance with outcomes that have a significant affect on preventing disparities. Examples of such outcomes are good prenatal care, normal birth-weight babies, and proven chronic care management. The civil rights model, therefore, which is based on an adversarial lawyer and court complex would no longer be the dominant model. The performance of physicians and

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<sup>86</sup> They are have a model act “Hospital Infection Disclosure Act” and encouraging activist to argue for passage. In some cases, sponsors of the legislation include the hospital association and patients and families who were infected. Lawyers who brought the lawsuits on behalf of the patients are also involved. *See* Rose Cuison Villazor, *Community Lawyering: An Approach to Addressing Inequalities in Access to Health Care for Poor, of Color and Immigrant Communities*, 8 NYU J. LEGIS & PUB POL’Y 35 (2004-2005).

the medical institutions, combined with carefully developed guidelines and benchmarks, would be the tools for reducing disparities.

A concern about new lawyer roles is uncertainty about who will be the advocates for disadvantaged groups. While educated individual patients can be effective at the patient-physician level, representatives of the interests of the disadvantaged groups are essential at the institutional and policy level. The move to consumer-driven health care contains the idea that consumers and patients, if they are provided information or economic incentives, can influence the system as well as obtain better, less expensive care. The advocate's role in assisting patients to participate can tie into the important work done on negotiation and dispute resolution. The personal health record is one tool that is being promoted as a way for consumers to be in control, particularly in relation to their physician and health care institution.<sup>87</sup> These exercises teach the patient to operate on the patient/client, institutional, and policy levels.<sup>88</sup> However, while this is partially true, as seen in the influence of physician information on consumer choice, there are substantial difficulties. The information is often flawed and many assert that the data is far from reliable. Many people cannot deal with the overwhelming number of choices. One example is the difficulties with the Medicare plan for pharmaceuticals, which is failing because of excessive information. People often need information tailored to their own health history; people with chronic disease may need assistance in locating information on what programs provide intensive disease management. On the institutional and policy level, the knowledge required for intervention is often sophisticated and requires skills such as accessing institutional policies, locating statutes and court cases, and discovering the places where intervention will be useful. These advocates for disadvantaged groups can be lawyers or reformist physicians committed to an all-inclusive health care system. These advocates play the role of assuring that barriers to access are removed; for example, ensuring the collection of data

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<sup>87</sup> See, [www.connectingforhealth.org](http://www.connectingforhealth.org).

<sup>88</sup> David Dominguez, *Getting Beyond Yes to Collaborative Justice: The Role of Negotiation in Community Lawyering*, 12 GEO. J. ON POVERTY L. & POL'Y 55 (2005).

on the number and characteristics of the uninsured that is reliable for program and policy development.<sup>89</sup> These advocates may also play an important role in diffusing the liability debate that is a barrier to implementing the new quality tools. They could advocate for the creation of monitoring institutions that assure that abusive and negligent behavior is prevented or sanctioned.<sup>90</sup>

### **C. Disaggregated but Necessary: The Role of Government**

The new deal view of government as the controlling, commanding presence is no longer accurate.<sup>91</sup> That view imagined that the social dimension of government should primarily be directed from Washington through national legislation implemented through administrative agencies issuing uniform regulations. State and local governments while still involved had a subordinate role. In the 1980s, with the move towards confidence in market based incentives, as the means to provide health care improvement, the confidence in external government regulation declined. There was also a belief in the return to the internal self-regulation model of the early 20<sup>th</sup> century.<sup>92</sup> However, in the recent discussions about new governance, the role of government is seen as necessary, even though it may no longer be the authoritative directing agency, as envisioned in the traditional command and control model.<sup>93</sup> Traditionally the government's primary role has been fiscal, through the public budgetary process.<sup>94</sup> Through its fiscal capacity the State can align various private players with public policy goals. It can use this power to play disaggregated roles: enactor of innovative regulation, crucial funder, active monitor,

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<sup>89</sup> *WIS. PUB. HEALTH AND HEALTH POL. INST.*, ISSUE BRIEF, No. 5 (October 2002).

<sup>90</sup> William M. Sage, *Unfinished Business: How Litigation Relates to Health Care Regulation*, 28 J. HEALTH POL. POL'Y & L. 387 (2003).

<sup>91</sup> MARK TUSHNET, *THE NEW CONSTITUTIONAL ORDER* (2003); William H. Simon, *Solving Problems v. Claiming Rights: The Pragmatist Challenge to Liberal Legalism*, 46 WM. & MARY L. REV. 127 (2004).

<sup>92</sup> Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825 (1995).

<sup>93</sup> Mark Schlesinger, *On Government's Role in the Crossing of Chasms*, 29 J. HEALTH POL. POL'Y & L. 1 (2004); see also Troyenn A. Brennan and Donald M. Berwick, *New Rules: Regulation, Markets, and the Quality of American Health Care* (1996).

<sup>94</sup> Carolyn Tuohy, *Agency, Contract, and Governance: Shifting Shapes of Accountability in the Health Care Arena* 28 J. HEALTH POL. POL'Y & L. 195, 210 (2003).

final sanctioner, orchestrator, and the justifier of programs. They are necessary for ultimate sanctioning, as sources of funding, and accountability for fair and equitable processes. Their participation in the collaboratives for example is essential to ensure that health care services, even if privatized, are fair, equitable, and effective. The government assumes a coordinating role in the implementation of health care services and organizes activities so that each actor can do whatever it does best. The various ways in which government can be involved includes facilitating collaboration, monitoring programs for effectiveness, collecting data, using regulation and funding to assure quality, correcting imbalances in participation, as when low-income patients and small businesses find it difficult to participate, and through sanctioning in order to ensure that actors participate in good faith.

#### **D. New Corporate Forms**

There is also a change in the governance of hospitals that is related to the increasing pressures for hospitals to be able to deliver quality care in a cost efficient manner. The existing governance structures cannot cope with pressures such as pay for performance regulations, benchmarking for quality care, and embedding technology. Hospitals are considering reorienting their systems in order to be able to successfully deal with these external pressures. Examples of what the hospitals are considering are: coordinating among other health care organizations, using internal regulatory systems such as ISO 9000, which are more industry based than professionally based, placing more responsibilities on boards of directors to ensure that physician groups and management are meeting the public goals, such as investment in information technology, and assuming a greater assumption of liability as a systems approach undercuts the single professional as the sole actor with exposure to liability.<sup>95</sup> As hospitals and clinics become larger integrated systems there is also a move towards standardization of benchmarks to be

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<sup>95</sup> Sarah Kaput, *Expanding the scope of Fiduciary Duties to Fill a Gap in the Law: The Role of Nonprofit Hospital Directors to Ensure Patient Safety*, 38 J. HEALTH L. 95 (2005).

received and improved internal communication. This results in the lawyers and compliance people needing to agree on systems in order for the information to be produced over the entire range of institutions and people responsible for institutions. Thus we see a crossing over between all institutions that are necessary to demonstrate value for the compensation to be paid. Thus the governing system requires more collaboration and interaction and undercuts the board of directors in a single institution. An example is lawyers and compliance professionals needing to work together to develop standards.<sup>96</sup> What is emerging in new governance is a blurring of the boundaries among for-profit institutions, large health care nonprofit organizations, and community-based agencies. The new collaborative sites include multiple actors from different organizational structures. These collaborations can orchestrate new ways of delivering health services and improve quality of services. The tools that can be used are: learning from each other, sharing of data, and the dissemination of peer benchmarks. In this process, there is a reconsideration of the traditional legal forms.

One example is the reassessing of nonprofit hospitals as a source of assistance and funding for expansion of access. There have been longstanding charity care pools that exist in many states that serve as sources of funding to meet the health care costs of uninsured people. These programs have been routinely criticized by advocates as being insufficiently integrated with the health care delivery system and with the individual needs of clients.<sup>97</sup> There is also a charitable requirement for nonprofit hospitals. This requirement has been poorly monitored by the government and insufficiently integrated with the health care needs of the uninsured. Recently class action lawsuits are being filed across the country against hospitals for their failure to provide services to the uninsured. These lawsuits, while largely

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<sup>96</sup> Barry P. Chaiken, Address at the Digital Healthcare Conference (June 9, 2005) (presentation on file with author).

<sup>97</sup> Elisabeth Benjamin & Kat Gabriesheski, *The Case for Reform: How New York State's Secret Hospital Charity Care Pool Funds Fail to Help Uninsured and Underinsured New Yorkers*, 8 NYU J. LEGIS & PUB POL'Y 5 (2004-2005).

unsuccessful up to now, have forced hospitals to consider how they link their service to the uninsured to their organizational status and to their community outreach.<sup>98</sup>

In Utah, the Governor is integrating hospital's charitable programs into the Medicaid program. This represents an example of public-private integration and orchestration discussed earlier, but it also is a redesign of the corporate form, where the state's interest is expressed, not only through the corporate non-profit law and the attorney general's authority to intervene in charities, but a way of the government directly working with the boards of directors in a common mission. The push by the federal government to fund community based health centers is based on their excellent record of providing equitable, quality care for poor and marginalized groups. Their services can be put together with large for-profits insurers and large nonprofit hospitals and clinics as part of a large amount of funding that will be administered by the groups. This allows for a variety of groups to do what they do best and also allow for structural monitoring and review from the dollars in the "deal."<sup>99</sup>

### **E. Alternative Dispute Resolution**

The disillusion with traditional litigation has been ongoing for several decades. The high costs, unequal access to lawyers, and poor fit between the social problem and the results of the litigation has engendered a series of proposed reforms. These proposed reforms move towards new types of redress, reduced use of lawyers, and improved health care outcomes.

Two additional types of dispute resolution are emerging as part of changing governance. The first is independent external review, a dispute resolution system for health care contract claims. The system developed out of dissatisfaction with the managed care system and is a way of reasserting physician peer review and curbing excesses in cost containment. The system, now enacted in almost all the States, is

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<sup>98</sup> Charles F. Sabel & William H. Simon, *Destabilization Rights: How Public Law Litigation Succeeds*, 117 HARV. L. REV. 1015 (2004); Guy Boulton, *Uninsured Get More Discounts*, MILWAUKEE JOURNAL SENTINEL, 5/16/05, at A1.

<sup>99</sup> See proposal for an access based test for nonprofit hospitals to justify their tax-exempt status. See John D. Columbo, *The Failure of Community Benefit*, 15 HEALTH MATRIX 29, 62 (2005).

primarily a paper review and almost eliminates lawyers from the system. The external review process is created through legislation but it is administered by private organizations certified by the state. These external review organizations use peer reviewers with very specific knowledge about the subject of the complaint. As one scholar notes “ they have a structural hybridity, a discursive marbling of demands for democratic control over profit-driven health care services together with calls for responsiveness to medical expertise.... It is a renegotiation of the roles of government, not a simple contraction or expansion.”<sup>100</sup> There is also a relationship between the complaint and improvement in the quality of the healthcare plan. The information about the complaint and the outcome is in the state agency and can be accessed by the agency. Public disclosure of the complaints and their resolution is an important component to encourage systemic changes within the health care plan.<sup>101</sup>

A second type of dispute resolution system that is emerging is a version of restorative justice. The traditional command and control regulatory system relies on inspection, regulation, and sanctions. For many health care facilities that are financed through government payments, there is a narrow range of financial viability. The use of fines as deterrence is not viable since the facilities, particularly nursing homes, are barely making it, and a failure will leave the state with the burden of relocating residents. Thus, as the push for high quality nursing homes continues, there is a need to come up with other means of correcting poor quality that does not involve heavy fining. One approach that is being discussed is to use the restorative justice model, often associated with the criminal justice system. The family members, residents and if possible community and advocacy groups meet together to discuss the problem and come

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<sup>100</sup> Nan D. Hunter, *Managed Process, Due Process: Structures of Accountability in Health Care*, at <http://ssrn.com/abstract+630482>.

<sup>101</sup> *Id.*

up with a plan for improvement. This is a first step prior to the institution of the traditional regulatory sanctions.<sup>102</sup>

## **F. New Regulatory Tools**

Another set of tools might be described as “hitting the physicians and hospitals in their wallets and their egos.” However, these tools also include incentives for internal systems where the public information that is now provided and the incentives for reimbursement tied to achieving outcomes also includes tools which encourage health care organizations to develop their own ways of providing this information. These three regulatory tools can be called: public information, financial incentives tied to efficiency, and regulations that allow the institutions to develop their own diverse ways of successfully meeting the standards.

There is widespread development of data about outcomes and commitment to protocols. Participation by the physicians and the other health care professionals is required in the development of the standards and the benchmarks for credibility. This information is sometimes collected by clinic, by hospital, and by physician. This information is often posted and accessible to all via the internet. These tools are different than the traditional regulation. Instead of rigid requirements issued after great debate, but often not revisited for many years, these systems are designed to be constantly updated and reviewed. The incentives are ongoing. There also are incentives for the system to be set up to achieve the goals of quality and access. They encourage teamwork within the organization since their outcomes are measured rather than compliance with specific numbers, such as the number of nurses on the floor. This information can affect performance through shaming and motivates the institutions to develop systems that obtain results. By gathering data and updating results on a regular basis, there is a constant reinforcement to the improving performance. Another approach to improving performance is to align the

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<sup>102</sup> John Braithwaite, et al., *The Governance of Health Safety and Quality* (2004) (manuscript on file with author).

incentives by tying financial payments to quality.<sup>103</sup> One commentator recently noted that “value for dollar” is now the game in health care.<sup>104</sup>

A third approach can be called management-based regulation. Management-based regulation is a mechanism that “directs regulated entities to engage in planning processes, that are self determined, to meet a particular public goal.”<sup>105</sup> Unlike technology-based regulations, that intervene at the action stage of organizational behavior, and performance-based regulation, management-based regulation is focused on planning.<sup>106</sup> Here again Medicare is taking the lead in their quality assessment and performance program to reduce medical errors, which is part of the broader Medicare conditions of participation. It is a planning model that is designed to allow hospital flexibility in designing programs.<sup>107</sup>

Medicare has recently heavily invested in collecting quality data and publicly disseminating the information. They have also been active in encouraging groups of stakeholders to develop the benchmarks and indicators that are used for the comparisons. There is still an ongoing debate about how effective economic incentives and public data dissemination are in motivating providers. Should the data be used to encourage internal systems reform by sharing the data exclusively within the organization, such as hospitals and physician practices. An alternative approach would be to publicly publish the data by individual hospital or physician to encourage consumer choice. The proponents of the public dissemination see that option as “a social movement wrapped in a business model.”<sup>108</sup> There is also an

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<sup>103</sup> Judith H. Hibbard et al., *Hospital Performance Reports: Impact on Quality, Market Share, and Regulation*, 24 HEALTH AFFAIRS 1150 (2005).

<sup>104</sup> Dave Riemer, Commentary by Dave Riemer at University of Wisconsin Medical School, April 4, 2005 (comments on file with author).

<sup>105</sup> John D. Blum, Combating Those Ugly Medical Errors-Its Time for a Hospital Regulatory Makeover! (June 2005) (unpublished manuscript, on file with Widener University Law Review).

<sup>106</sup> Cary Coglianese and David Lazer, *Management Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 L. & Soc’y Rev. 691, 691 (2003).

<sup>107</sup> John D. Blum, Combating Those Ugly Medical Errors-Its Time for a Hospital Regulatory Makeover! (June 2005) (unpublished manuscript, on file with Widener University Law Review).

<sup>108</sup> Mark Xistraas, Address at Colloquium on Health Care Data Collection and Reporting (February 7, 2005) (comments on file with author).

issue of publicness of the process of data collection and dissemination. If the collaborative sites that are producing and dissemination the information are not adequately transparent the process could become insular and self-protective. One commentator has said that the control of the data and its dissemination requires adequate public oversight; otherwise our democracy has become a “banana republic.”<sup>109</sup>

#### **IV. Coexistence: Dynamic Between Old and New, Orchestrating Multi-pronged Strategies, and Integrating Legal Values**

The question is whether the innovations that are emerging can reform health care while assuring participation, fairness, equity and accountability. There is also the question as to the effectiveness of new governance and soft law to relate to the existing complex regulatory system. These three stories about resolving health care problems are descriptions of works in progress and as one observer noted, “we are still torn between the old and the new.”<sup>110</sup> These innovations can be seen as providing some answers to the critiques. These innovations share certain attributes. The first is incrementalism, that is they proceed from bottom up while incorporating an understanding of the larger change. Thus, they require multilevel interactions that are ongoing between the bottom and the top. Second, they reflect shared expertise between the professionals, the community, and the patient/consumer. This type of networking can also be seen in the melding of public and private entities and the crossing between traditional administrative and corporate law. The networks and new knowledge also allow interaction between sectors, such as health care research and public health. The role of government therefore in this governance regime is also

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<sup>109</sup> John Chapin, Health Data in a Banana Republic (Jan. 2005) (unpublished manuscript, on file with author).

<sup>110</sup> Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155 (2004).

multifaceted and plays a role using various techniques to perform various disaggregated functions. This also results in the use of new procedures not based on the traditional legal methods. Finally, there is extensive use of data collection that can be the basis for public visibility and for the use of economic incentives.

There are three examples of coexistence between old governance/hard law and new governance and soft law. The first is dealing with medical error, where old and new models coexist as alternatives and potentially as rivals. The second is where a government agency takes on the whole range of new governance techniques and employs them as part of their regulatory and funding functions. The outstanding example of this is the Medicare program of the Centers for Medicare and Medicaid Services. The third route is the integration of traditional legal values as part of the new governance approaches. These include the incorporation of monitoring to ensure participation, with special attention to disadvantaged groups, assuring commitment to eliminating discrimination through maintenance of equal protection, and linking the right to health care to the achievement of a robust economy.

#### **A. Dynamic Between Old and New**

Coexistence between new governance and soft law and the traditional hard law can occur through a dynamic rivalry. One example of the interrelationship between the two is the effort to move from the traditional medical malpractice and administrative sanctioning of physicians to a systemic increase in quality.<sup>111</sup> The old governance system relied on medical malpractice and administrative physician sanctioning to guarantee quality and compensate injured parties. However, the existing malpractice legal structure is now a barrier to the development of a new framework that gets physician buy-in, adequately compensates patients for poor medical outcomes and creates systemic processes to avoid medical errors. There is widespread agreement that the malpractice litigation system fails to compensate injured parties

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<sup>111</sup> Mello et al. also discuss the tension between tort law and other regulatory approaches. They cite this area as one of the structural issues for what they call rational regulation. See Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 411 (2005).

and to deter future negligence. Proponents of the quality assurance system assert that it will do a better job of deterring negligent behavior as well as preventing unnecessary errors. However, there is not yet a consensus as to how to compensate patients who are injured through negligent or non-negligent behaviors. Many alternatives on how to compensate patients who are injured have been proffered: no-fault insurance, enterprise liability or new types of redress such as medical courts or arbitration.<sup>112</sup>

## **B. Orchestrating Multi-pronged Strategies**

In some cases there is coexistence between a traditional government agency and new governance techniques. They are yoked in a multi-pronged strategy that deals with complex problems. Orchestration is one example of a multi-pronged strategy. Orchestration uses new governance techniques to integrate new knowledge, encourage innovation, and allow for diversity. The government agency, however, relies on its traditional regulatory and funding roles to provide baseline incentives for participation in the new governance processes.<sup>113</sup>

The role of the Center for Medicare and Medicaid Services (CMS) is a dramatic example. CMS is embarking on a multi-pronged strategy to improve quality and contain costs using new governance techniques for Medicare. It is currently funding pay for performance pilot projects throughout the country that may be the basis for future widespread use.<sup>114</sup> The pay for performance criteria will be used as a condition of participation for hospitals seeking to receive Medicare reimbursements. They are creating forums for deliberation and action for quality improvement. For example, the Hospital Quality Alliance

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<sup>112</sup> Paul C. Weiler, *Fixing the Tail: The Place of Malpractice in Health Care Reform*, 47 RUTGERS L. REV. 1157 (1995).

<sup>113</sup> Mello et al. term this form of coexistence “pluralistic regulatory environment.” Mello et al., *supra* note , at 381.

<sup>114</sup> Press Release, Center for Medicare and Medicaid Services, Medicare “Pay For Performance (P4P)” Initiates (Jan. 31, 2005), at <http://www.cms.hhs.gov/media/press/release.asp?Counter=1342>.

is a public-private partnership designed to produce published consumer information coupled with health care quality improvement.<sup>115</sup> CMS recently required the submission of hospital quality data as a condition of compliance in order to receive Medicare funding.<sup>116</sup> This data is now displayed on a website. They have initiated other substantial publication of consumer information starting with comparative nursing home quality indicators.<sup>117</sup> CMS initiated a discussion among many stakeholders on how Medicare information can be used by beneficiaries in medical health records. It is one of several initiatives put forth in response to “President Bush’s call for Americans to access their health records electronically within ten years.”<sup>118</sup>

### **C. Integrating Legal Values**

The new deal/great society model for governance emphasized the need for universal “rights,” based on constitutional or statutory law. The function of rights can be seen as coexisting with new governance modes. This coexistence can be seen in the way traditional legal values must be maintained in order for new governance to be effective and legitimate. Three approaches to health care reflect the coexistence of these new governance techniques with legal values: inclusion in universal access, equity in health care treatment, and participation and transparency in health care decision making.

#### **1. Inclusion**

The long-standing battle for a “right to health care” underlies many of the campaigns for universal provision of health care coverage. The failure to achieve a constitutional right was a major disappointment of the 1960s and 1970s “war on poverty.” More recently, the entitlement to Medicaid coverage, a partial type of “right,” was seriously threatened in a Congressional battle and many of the new programs do not

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<sup>115</sup> Marybeth Farquhar New Governance in Hospital Quality Improvement: The Hospital Quality Alliance (June 2005) (unpublished manuscript, on file with author).

<sup>116</sup> *Id.*

<sup>117</sup> Nursing Home Compare, <http://www.medicare.gov/NHCompare/home.asp>.

<sup>118</sup> Press Release, Center for Medicare and Medicaid Services, Special Open Door Forum: Personal Health Records (July 1, 2005), <http://www.cms.hhs.gov/opendoor/PHRannouncementfinal.pdf>.

have entitlements.<sup>119</sup> The elimination of the entitlement status of the major welfare program for poor people—Aid for Dependent Children (AFDC) —was a tremendous blow for the progressives who, since the new deal, had dreamed of the adoption of the European “social citizenship” model.<sup>120</sup> The maintenance of the entitlement to Medicaid is a continual battle. The battle over entitlements, coupled with the Clinton plan failure, undermined the progressive belief that an entitlement/rights approach was a likely route to universal coverage. Constitutional approaches have proved ineffective and recent court decisions have further undermined the court-constitutional approach.

What is needed is a conceptualization of the relationship between hard law entitlements with soft law techniques such as experimental expansions of coverage and linking private employer based programs with public coverage.<sup>121</sup> Universal programs are necessary; the more a program is just for the poor the more it is likely to be cut. The merger of public and private programs is a way of achieving universal coverage where the poor will not be targets of inadequate funding and poor quality. In the access area, the importance of a commitment to universality continues. Recent proposals have indicated a wider base of support among business and conservative legislators for universal coverage based on the “business case.” Some type of “hard law” commitment may be a necessity to keep the attention on the importance of universality. But, a “right” is not sufficient if there is inadequate care and excessive patient payment contribution.<sup>122</sup> Realizing this coexistence is not easy. Recent state battles over

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<sup>119</sup> Sara Rosenbaum, et al., *Public Health Insurance Design for Children: The Evolution from Medicaid to SCHIP*, 1 *Journal of Health & Biomedical Law* 1, 41 (2004).

<sup>120</sup> JOEL F. HANDLER ET AL., *SOCIAL CITIZENSHIP AND WORKFARE IN THE UNITED STATES AND WESTERN EUROPE: THE PARADOX OF INCLUSION* (2004).

<sup>121</sup> See Tamara K. Hervey, *The European Union and the Governance of Health Care* (March 14, 2005) (forthcoming in *New Approaches to Governance in the European Union and the United States*, De Burca & Scott eds.).

<sup>122</sup> Sara Rosenbaum, et al., *Public Health Insurance Design for Children: The Evolution from Medicaid to SCHIP*, 1 *Journal of Health & Biomedical Law* 1, 41 (2004); TIMOTHY STOLTZFUS JOST, *DISENTITLEMENT?: THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE* (2003). See also, Bill J. Wright et al., *The Impact of Increased Cost Sharing on Medicaid Enrollees*, 24 *HEALTH AFFAIRS* 1106 (2005).

maintaining Medicaid expansion programs have demonstrated the conflict between court mandates and the more flexible non-entitlement approaches.<sup>123</sup> If the standards are not enforceable, there will be a tendency to cut back when funding is tight. The recent budget battles have demonstrated a strong commitment to expanded health care by Governors on a bi-partisan basis. But the fragility of the expanded programs demonstrate that a combination of diverse state programs, that merge public and private coverage, has to be incorporated into a framework that allows for court and public scrutiny.

## **2. Equity**

There are major initiatives underway to reduce disparities in race and ethnicity, but the role of rights is decentered in the new approaches. There is reliance instead on quality tools such as benchmarking, nationally accepted protocols for best practice, and patient self-management to eliminate disparities. Preliminary results show that these processes may be effective in reducing racial disparities. The move to using the “law of quality compliance” includes soft law instruments such as benchmarking, data collection, and reporting.<sup>124</sup> However, the “law of civil rights” can be combined with the “law of quality compliance.” The quality compliance techniques require collection of data and a commitment by the providers and institutions to collect, examine and utilize the data. It also requires a sharing of information across local groups and at the state and national level. Community and patient participation in the system for quality are required for the protocols to be successful. In order for there to be confidence that the standards and protocols are being followed, there must be an ability to monitor the work of the institutions, such as hospitals and clinics. The civil rights community has maintained an interest in health care and the potential for legal remedies remains. Their role can include ensuring that public data dissemination is available and usable by outside groups. Specific monitoring systems can be set up, at the

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<sup>123</sup> See [www.tennessee.gov/governor/tenncare.htm](http://www.tennessee.gov/governor/tenncare.htm); [http://tennessean.com/opinion/nashville-eye/archives/05/01/63290285.shtml?Element\\_ID=63290285](http://tennessean.com/opinion/nashville-eye/archives/05/01/63290285.shtml?Element_ID=63290285).

<sup>124</sup> Sara Rosenbaum, , Symposium, Racial and Ethnic Disparities in Health Care Treatment, The Harvard Civil Rights Project (May 18, 2004) (unpublished manuscript, on file with author).

community level, the state level, the self-regulatory body level, or the national level. Without these checks it is difficult to monitor that the techniques are in place and effective. Once it has been shown that the use of new governance techniques can have positive results, it may be possible to use litigation to create pressure on health care providers to adopt the new processes. In that way, the simultaneous presence of anti-discrimination law and new quality improvement processes may make possible progress not previously achievable.

### **3. Participation and Transparency**

If important and affected groups are left out of the process, it is likely to lose legitimacy. This may mean that special efforts must be made to ensure participation of underorganized and underrepresented groups, and to be sure well organized groups see it in their interest to participate. One approach to ensure participation is providing a system for explicit measurement of the participation of disadvantaged groups in these new sites.<sup>125</sup> This requires guidelines for participation and monitoring to ensure that the guidelines are being met. Another approach is to provide a process where groups who view themselves as excluded from the process can challenge the transparency and effectiveness of the governance scheme. A final approach would be to develop a process where actors who are refusing to collaborate in these new alliances are sanctioned. Some type of sanctioning might be necessary to provide the incentives for participation.

A second crucial value is transparency. The processes in order to be legitimate must be visible and accountable. The sites for deliberation, a crucial element in new governance decision making, should allow their work to be visible to interested parties. The issues involving access to electronic records raise important issues, such as the control of valuable social information. The interest in personal health

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<sup>125</sup> Brandon L. Garrett & James S. Liebman, *Experimentalist Equal Protection*, 22 YALE L. & POL'Y REV. 261, 321 (2004).

records raises interesting questions about the availability of the information and the interaction between the patient and the health care institutions. The coexistence of the need for flexible public private spaces and information has to be balanced with the ability to hold the actors accountable for their outcomes.<sup>126</sup>

### **Conclusion**

A reform process is underway. The innovations that initiate and facilitate reform are in progress. These innovations challenge conventional institutions, roles, and professions. They also challenge the way we participate in society and our view of how government and law can operate. They also reveal that coexistence of new governance with older governance systems is possible and desirable. One question is what will be the continuing relationship of the new techniques to the older system. One view is that the resistance of key actors to change and the inability to demonstrate improved outcomes will roll back these fledgling innovations. Another view is that the coexistence is stable in many areas and will achieve success by staying the course. A third view is that coexistence is a transitional stage and more radical transformation is ahead.

Nonetheless, this is an interesting time to look at health care. It is exciting for those interested in resolving long-standing health care conundrums. It is also an opportunity to examine the ways governance and law are changing across many sectors in the United States and internationally.

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<sup>126</sup> Patti Brennan, Address at the Digital Healthcare Conference (June 9, 2005) (presentation on file with author).

