Reforming Health Reform: Revisiting the Process of Governance

John D. Blum
*Loyola University Chicago, School of Law, jblum@luc.edu*

Follow this and additional works at: http://lawecommons.luc.edu/facpubs

Part of the *Health Law and Policy Commons*

**Recommended Citation**


This Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in Faculty Publications & Other Works by an authorized administrator of LAW eCommons. For more information, please contact law-library@luc.edu.
Reforming Health Reform: Revisiting the Process of Governance

John D. Blum

The Patient Protection and Affordable Care Act (ACA) is arguably the most ambitious piece of health legislation enacted since the passage of the Medicare and Medicaid programs. The law creates a massive extension of federal health insurance through subsidies and mandates, ushers in multiple reforms of existing federal health programs, and introduces a host of new initiatives designed to reform the health care delivery system. While the broad outlines of the ACA reform have been widely discussed, the details of these discernable parts are complex and illusive. As the rigorous implementation calendar unfolds, massive new regulatory details are both being proposed and in some cases solidified, underscoring the complexities of superimposing changes onto the web of American health care. No doubt there are many vantage points from which to view ACA, and all of its component parts, interwoven to form the fabric of universal insurance coverage, as

1 M.H.S., J.D. John J. Waldron Research Professor, Loyola University Chicago School of Law.
3 See id.
5 See generally Jost, supra note 4.
well as those issues that are disparate, singularly reflecting threads of an array of initiatives. In spite of its enormity, the ACA legislation does not stand alone but is linked to major changes in information technology in the Hi-Tech Act and also is part of the fabric of Medicare, Medicaid, ERISA, and the tax code.7

This essay is not intended to probe the details of the reform law, other than in the most general way, rather it is written to consider the process of law that underpins this effort, namely the role of regulatory procedures as a foundational driver of ACA’s collective reforms. The piece initially will identify the broad directions that are included in the health reform legislation and offer a number of reflections on characteristics of the law which are emerging in statutory implementation. The essay then will consider the goals of the regulatory process ushered in by ACA beyond rote compliance with legislative mandates. The final part of the paper will posit a number of suggestions for reforming the mechanics of regulations based in large part on current directions in US administrative law ushered in by Executive Order 13563, and linked to larger trends in administrative law processes within the context of what is collectively referred to as new governance.

The Big Picture

On March 23, 2010 President Obama signed the Patient Protection and Affordable Care Act and subsequently on March 30, a companion bill of amendments, the Health Care and Education Reconciliation Act.8 This massive new legislation package does many things, but in broadest terms, the law expands health insurance coverage to 32 million Americans and initiates a series of reforms affecting both public and private health insurance, and in so doing revamps the current health care delivery system.9 Within the

9 See id.
Reforming Health Reform

wide spectrum noted, nine areas can be singled out which collectively capture the spirit of the ACA law starting with what is arguably the best known provision of the law, the individual mandate that requires almost all Americans to purchase health insurance. Secondly, ACA authorizes the creation of new state based health coverage networks referred to as health insurance exchanges, which will provide consumers with various government sanctioned insurance products. The third major element of the reform entails a series of private insurance measures that includes a ban on pre-existing conditions, restrictions on policy rescissions and limitations on rate increases, broadly expanding federal oversight in an area traditionally dominated by state law. The fourth focal of ACA concerns wide ranging reforms and extensions of both the Medicare and Medicaid programs, building on the long reinvention of these two public entitlements. Fifth, the ACA legislation contains a wide array of revenue measures designed to make reform fiscally viable, including thirteen new taxes. By far the most significant fiscal measures in the legislation are ones that cut Medicare reimbursement to physicians and hospitals, estimated at reducing those expenditures by $132 billion over ten years. The sixth area of focus in ACA concerns measures that deal with employers; there are grandfathering provisions in the law which encourages the continuation of health benefit plans, as well as a provision that levies penalties against large employers who refuse to offer health care coverage. In the case of small employers tax credits are offered to underwrite the purchase of employee health insurance. The seventh general focal point of the health reform law is the addition of a new, voluntary long-term insurance plan which provides a cash benefit to assist individuals in two major life

11 Id. § 18041.
12 Id. § 18001; see also id. § 300gg-12.
13 Wash. Post, supra note 7, at pt. II, chs. 6, 12.
14 Id. at ch. 13.
15 Id. at ch. 6.
conditions. Eight, ACA contains a number of provisions that support wellness approaches to health, and provides a payment waiver under Medicare for several preventive health measures. The ninth major legislative stream can be categorized under the broad heading of quality and involves a series of Medicare reimbursement demonstrations that entail payment reforms that will spark coordinated care and evidenced based medicine.

While broad templates are helpful in garnering a generic awareness of this law, exploration of the underlying statutory details in ACA reveals complexities quickly lost in generalities. Underscoring these complexities is the ambitious programmatic timetable putting the respective elements of the health reform legislation into operation, primarily through agency rulemaking processes. The timetable is a rigorous one as the law mandates implementation of key provisions of the statute in fairly rapid order. From 2010 through 2018, 73 measures in ACA must be actualized by the Department of Health and Human Services through the Centers for Medicare and Medicaid, either singularly or in conjunction with Department of Labor and the Internal Revenue Service. Less than one year after the passage of the law, several major sets of regulation have been issued presenting a portrait of the details necessitated by the respective measures in this legislative scheme.

---

18 Id. § 300gg-13.
19 Id. § 1315a.
20 Id. § 280j.
22 Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968 (Feb. 23, 2011) (to be codified at 45 C.F.R. pt. 88); see also Medicare Program; Home Health Prospective Payment System Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices, 75 Fed. Reg. 70372 (Nov. 17, 2010) (to be codified in scattered parts of 42 C.F.R.); see also Patient Protection and Affordable Care Act: Pre-Existing Condition Exclusions, Lifetime and Annual
Observations

The sum total of the legislation and emerging new regulations sparks a number of observations about overall characteristics of this law. Those observations include reflections on volume, complexity, cost, regulatory absorption and industry stabilization. At its most basic level, what is striking about ACA, is the sheer volume of law that has been enacted, and the additional law that will emerge from implementation, when the statute on its face is combined with a massive amount of new regulatory mandates.23 Even in a field characterized by extensive regulation, the ACA law is striking in its sheer size and commensurate details.24 No doubt, in and of itself, volume says very little about the propriety of a law. Indeed volume is the anticipated byproduct of such a major legislative undertaking, particularly one that fundamentally alters so much of the landscape of government health policy. It also follows that in the midst of ACA’s voluminous changes and initiatives, a myriad of ambiguities and questions will abound, necessitating even more detailed regulatory responses. The segmented nature of the health sector requires extensive tailoring of mandates to particular types of providers furthering fueling a need for details and sparking yet more regulatory mass.

Volume is not without consequence, and the excessive weight of new and intricate details can become a hindrance to understanding and implementation. There is very little in the ACA law that does not raise considerable complexities, and an exploration of the initial regulatory output that has occurred since the passage of the law is a ready testament to the intricacies of

enforcement.²⁵ ACA forms a statutory web that is spun around existing Medicare and Medicaid laws. These laws, in particular, serve as core building blocks of ACA, and the framework of reform can only be actualized in reference to existing federal laws not only dealing with public health insurance, but also laws concerning employee benefits and taxes. Additionally, health reforms under ACA must be seen in conjunction with the 2009 Health Information Technology for Economic and Clinical Health (HITECH).²⁶ The Hi-tech Act is a critical piece of system infrastructure which places the federal government at the heart of developing an electronic medical record system, without which the goals of health reform cannot be accomplished.²⁷ Seen together with ACA, Hi-tech implementation and compliance further muddy the waters of regulatory complexity.²⁸

State governments play a direct role in ACA through the creation of health exchanges and the expansion of Medicaid and clearly in those areas the picture of reform will be shaped by the nature of regional government responses. No doubt the federal authorities will provide oversight of state regulatory measures, pushing for certain uniformity but for political and practical reasons, some level of state regulatory idiosyncrasies must be accommodated.²⁹ In addition, as health reform unfolds, the current

²⁷ Id.
²⁸ 2010 was a banner year for health regulations as ACA and the Hi-tech Act are the most viable manifestations of change. For another perspective on an industry in transition, see Melanie Evans, Gambling on Change, MOD. HEALTHCARE, Jan. 31, 2011, at 6.
²⁹ Perhaps the most extreme example of state push back on reform is Alaska, which has indicated it will not seek Federal grants to establish health insurance exchanges. Alaska’s position is more extreme than other states that are proceeding to implement the ACA law, but no doubt charting their courses in doing so. See Michael Marios, Alaska Cites Court Ruling in Refusing Federal Health-Care Money, BLOOMBERG NEWS, Feb. 17, 2011, http://www.bloomberg.com/news/2011-02-18/alaska-s-parnell-cites-court-ruling-in-refusing-federal-health-care-money.html.
structure of basic state health regulations in core areas such as licensure, and public health will need to change, sparking further complexity in the delivery system. Beyond federal and state regulatory developments, the many health care associations that act as private regulators must be considered in that the array of ACA reforms will likely trigger changes in various standards that have developed in virtually all areas of health delivery. For example, the increasingly important area of patient safety, deeply embedded in health reform, is an area that must be linked to both state regulatory activities, as well as to the dozen or so entities which are active in setting policies and standards in the area.

Perhaps the most universal concern triggered by the ACA legislation is that it is over cost. At the macro level the projections of the Congressional Budget Office (CBO) that ACA will reduce the budget deficit over ten years by $100 billion have framed an ongoing debate surrounding the law. CBO projections have been countered by analysts whose cost evaluations are far more negative about the long term fiscal realities attached to the law. The issue of regulatory cost is not, however, one that deals only with multi-year implications, but resides in the more immediate concerns of employers, insurers, providers and individual consumers about

For example, The Joint Commission sponsors a very active program of hospital accreditation that covers virtually all aspects of facility operations. See THE JOINT COMMISSION, 2011 ACCREDITATION PROCESS GUIDE FOR HOSPITALS (2010). It is likely that a series of changes ushered in by the ACA will eventually be felt in hospital accreditation, as well as in private sector programs affecting other providers.

Patient safety encompasses an array of public and private efforts that have resulted in various specifications and guidelines. Among the private actors who have influenced this field are the National Quality Forum, Institute for Health Care Improvement, National Patient Safety Foundation, America Society of Professional in Patient Safety, and The Leap Frog Group for Patient Safety.


present financial implications of ACA compliance. Over a long period reform should lead to a more efficient delivery system with reduced costs and higher quality, but getting there through the details of legislative implementation may prove to be costly.34

Clearly regulators are highly cognizant of cost factors, and administrative law processes demand considerable financial assessment of new mandates. However, such efforts generally focus on given initiatives and do not reflect the aggregate economic impacts of regulatory compliance across a wide spectrum of requirements. Furthermore, on an individual rule basis, impact analyses rest on certain methodologies and assumptions that may not be shared outside the halls of bureaucracy.35 An example within ACA of disagreement over regulatory costs can be found in the divergent analyses concerning the financial impacts of a proposed rule in the area of hospital reimbursement, namely value based purchasing, a system of reimbursing hospitals based on


35 There is a much longer history of regulatory impact analyses in the environmental area, but controversy surrounding this process can be found in Health Care as well. For example, due to pressure from the field, four of six Centers for Medicare and Medicaid Services (CMS) rules for concerning Medicaid reforms were placed under a Congressional Moratorium. This episode, chronicled by the Kaiser Family Foundation, demonstrates the level of tension that can occur in governance that not only splits the regulations and the regulated, but spills over into inter-governmental disputes. See KAISER COMMISSION ON MEDICAID AND THE UNINSURED, MEDICAID: OVERVIEW AND IMPACT OF NEW REGULATION 1, 1 (Jan. 2008), available at http://www.kff.org/medicaid/upload/7739.pdf.
performance standards.\(^{36}\) According to the regulatory impact done by the Centers for Medicare and Medicaid Services, the value based purchasing rule would result in an equal number of hospitals receiving a 1% increase or decrease in payments.\(^{37}\) On the other hand industry experts projected that the new value based purchasing initiative would result in 75% of hospitals facing potential losses.\(^{38}\) The disagreement over the impacts of value based purchasing maybe attributed to the typical jousting between regulator and regulated, as well as a disagreement over the long term benefits of a rule taken by government, versus an industry perspective that projects significant losses in the short term as a result of the new payment methodology.

A fourth observation that can be made about ACA concerns whether the provisions of the statute and the unfolding regulations, taken together with other new and existing mandates can be absorbed by the field. Simply stated will the health care delivery industry be able to respond to the continued layering of regulatory requirements. The challenges of ACA compliance are wide ranging, encompassing not only health care institutions and providers but also insurers, employers, state regulators, as well the federal bureaucracy.\(^{39}\) Those issues directly related to the delivery of patient care will likely be the most challenging new requirements that emerge in health reform. Not only will providers need to understand new mandates, but they must harmonize those mandates with complex and unsettled areas of current compliance, while achieving their primary mission of providing medical care, in


\(^{37}\) Id. at 2487.


\(^{39}\) For a broad perspective on ACA’s impacts, see generally WASH. POST, supra note 7.
situations that may be fiscally tenuous. While the bureaucracy may provide guidance for response to individual regulations, as was noted, regulators are not overly attuned to the collective impacts of new mandates. There does not appear to have been a particular focus on the part of either legislators or regulators about how ACA might impact ongoing, daily operations of the regulated parties or on how new mandates would be harmonized with existing regulations; rather, the attention of those promoting ACA has been on field change. There is a danger in a regulatory movement disconnected from operational realities that compliance occurs solely to meet mandates and may be accompanied by a lack of understanding and commitment to systemic change on the part of the regulated. The broader goals of reform underlying ACA maybe viewed by those in the field as just another in a long series of compliance requirements; concerns about systemic reform become matters that reside only in the halls of government.

Over time a certain level of equilibrium is achieved in any area of regulation in which the regulated grow accustomed to new mandates and necessary accommodations are made to adjust to particular changes. It can be argued that as the health sector responds to new ACA requirements the disruptions to the enterprise of health insurance and delivery will be lessened, as mandated changes become incorporated into operations. In point of fact, however, a major underlying goal of health reform is disruption and

---

40 For a sense of the wide array of regulatory mandates, see Carhart et al., supra note 24.
the reinvention of the sector. As such, the new regulatory mandates in ACA, combined with the development of medical informatics, will deliberately reshape the face of health care in ways that will cause regulated actors to reform, be absorbed by others, or disappear from the health care stage. Certainly ACA's greatest structural innovation, the integrated care network known as the Accountable Care Organization (ACO), is intended to reinvent the delivery system. The business models of the ACO have yet to be determined but if these new entities emerge as intended, they will reshape the structural nature of health care in significant ways. Disruption via law may be totally warranted, but the impacts of new oversight provisions should be carefully gauged as sound governance requires application of methodologies and structures that are operationally viable. Even the most carefully crafted regulatory program is subject to unintended consequences and market absorption of new mandates can occur in ways that may depart from legislative intent.


45 See CHRISTENSEN ET AL., supra note 44, at ch. 3, for an interesting discussion of business trends in health care written prior to ACA but particularly germane when viewed in this context. It is difficult to predict what the implications will be for individual actors as a result of ACA and Hi-Tech but undoubtedly there will be great changes in the health care marketplace. See Associated Press, Will Safety Net Hospitals Survive Health Reform?, MSNBC.COM, Sept. 8, 2009, http://www.msnbc.msn.com/id/32672409/ns/health-health-care/t/will-safety-net-hospitals-survive-health-reform.


Any observations about health reform must be made cautiously as the environment surrounding this initiative is highly unsettled. Political and legal pressures will undoubtedly result in major changes to the law, and it is not unlikely that the individual mandate requiring the purchase of health insurance may be redrafted or possibly eliminated. Still, even with many changes in the wind, it is likely that the eventual shape of ACA will be heavily imbued with new regulations and procedures, driven by the formats of legal oversight, and channeled through rule making processes. Certainly regulation is not unique to health care: other sectors have undergone dramatic and large scale changes sparked by the operatus of public authority, with the results being voluminous new control measures. But what separates health care from other regulated sectors is a constant reinvention of structures and oversight policies driven by the elusive goal of improving quality at a reduced cost.

50 For example, massive new requirements have been legislated changing the financial services industry under the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).
51 While the regulation of most industries has changed over time, the health sector is characterized by frequent changes in the scope and nature of federal oversights. Perhaps the best example of the size and fluidity of federal health regulation can be found in the Medicare program. Since its inception in 1965 Medicare has been under continual revision moving from a cost based reimbursement program into a broad prospective payment structure with numerous ongoing attempts to link up reimbursement with improvements in the quality of health care. See Henry J. Aaron et al., Medicare Reform, The Stakes, in REFORMING MEDICARE: OPTIONS, TRADEOFFS, OPPORTUNITIES ch. 1 (2008).
Rethinking Process

It may seem obvious to most observers that the goals of regulation are to implement statutory mandates in a manner that fits the directive at hand, while meeting the dictates of administrative law and agency policy.\(^5\) Undoubtedly, crafting rules that are statutorily compliant requires a highly complex set of decisions to actualize the law in ways that are transparent, equitable, and efficient, requiring considerable judgment. The interim final and proposed rules that have emerged in the ACA context are noteworthy for actualizing current programmatic mandates. However, these regulations break no new ground in governance; rather, they follow well trodden pathways. In fairness it should be noted that regulators, under considerable pressure to meet rulemaking timetables and to produce workable and comprehensive rules, have little time to ponder the merits of reforming administrative processes. Nevertheless, it is not unreasonable at a point of such major change in American health care to posit the argument that constructive changes in agency procedures would yield better, more workable regulatory outputs. The health care industry in 2011 is too splintered to be effectively regulated by a one size fits all approach, and there is a danger in an overbearing uniformity that the creativity and innovation fundamental to the success of broad reform initiatives such as ACA could be stifled. The challenge becomes one of identifying viable processes in ongoing, and new regulatory initiatives like ACA, which are constructively innovative, and command support from both regulators and regulated.

Change in administrative process is not a novel phenomena but an ongoing reality, as is evident from even a casual perusal of the Federal Register.\(^5\) Chief among a number of evaluation processes is the development of a regulatory impact statement by agencies, which requires a detailed analysis of major rules, focusing

\(^{52}\) See generally KENNETH F. WARREN, ADMINISTRATIVE LAW IN THE POLITICAL SYSTEM (4th ed. 2004).

\(^{53}\) Id. at 97.
on costs, benefits, and approaches to regulation. For thirty years, the Office of Management and Budget has reviewed agency rules and currently through its Office of Information and Regulatory Affairs (OIRA) evaluates drafts of agency rules to insure that they are compatible with overall Administration goals in given areas. OIRA acts as both monitor and advisor on process issues, as well as a type of intermediary between government and a regulated industry such as health care.

Recently President Obama issued a new Executive Order 13563, “Improving Regulation and Regulatory Review.” Executive Order 13563 affirms and supplements a prior Executive Order 12866 that in 1994 had articulated core principles of regulation which focus on costs, benefits and burdens of regulation. The 1994 rule may have ushered in process changes, but certainly did not alleviate private sector anxieties over regulation or spark major creativity in administrative rule making. The more recently issued EO 13563 represents a recognition that further changes need to be made in administrative processes and the directive opens up greater potential for reform of agency procedures. In addition to reiterating the core principles of regulation issued in 1994, EO 13563 stresses public participation in rule making, adoption of flexible approaches to regulation, emphasis on the use of objective

Reforming Health Reform

scientific and technical information in shaping guidelines, and calls for a retrospective analysis and commensurate modification of existing regulations. While the responses of given agencies such as the Department of Health and Human Services to the new executive order are yet to be realized, it is a significant statement about the importance of regulatory process revision, and certainly signals an understanding of the Obama Administration about longstanding problems in this area of law.

New Governance

What is particularly interesting about EO 13563 is that it appears to fit into a broader context of comparative regulatory reforms often referred to as new governance. Although it is difficult to succinctly describe the broad and somewhat eclectic area of new governance, it represents a growing awareness of the limitations and propriety of traditional government structures in framing and controlling a given field, such as health care. New governance has sparked a number of novel approaches to regulation that move toward much less proscriptive processes; it does not abandon public mandates, but calls for such mandates to be more fluid and developed in a far more collaborative and anecdotal fashion. The new governance critics of command and control processes see traditional administrative law formats as stifling innovation, in that such processes are rigid and formulative and can become impediments to real reform.

59 Whelan & Russell, supra note 43.
60 John Blum, A Revisionist Model of Hospital Licensure, 2 REG. & GOVERNANCE 48, 52 (2008).
61 Id.
Among the better known approaches to new governance is responsive regulation, a system of governance that allows for the adoption of regulatory strategies that move between the poles of persuasion and command and control. Characteristic of responsive regulation is a regulatory pyramid that starts with voluntarism at its base, and moves to market controls, self regulation, oversight of self regulation (meta-regulation) and ends with traditional agency rule making. Designed by Australian academic John Braithwaite, responsive regulation rests on the idea that informal interventions to address matters of governance, together with information feedback being regularly provided to regulated entities, are more effective than traditional mechanisms. Responsive regulation does not obfuscate the need for public oversight, but rather provides a continuum of options based on the behavior of the regulated and the need for greater or lesser direction. Other new governance models call for public/private partnerships in health care specifically to foster working collaborations that are directed to service goals for given populations, and share the commonality of other process reforms in being tailored and flexible.

EO 13563, noted previously, does not adopt any particular regulatory reform model that would be recognized in the lexicon of new governance but rather represents a major departure in philosophy and potential approach to agency rule making that can be seen as a starting point for meaningful change in this area. EO 13563 is supportive of developing regulations that are less costly, promote competition and innovation, plus allows for directives that are based on performance standards as opposed to specific rule compliance requirements; all elements seen in various new governance models. Additionally EO 13563 allows for different regulatory requirements to be applied to large and small entities, and in some cases permits the granting of partial or total

---

64 Id.
65 Id.
66 Id.
exemptions from various types of regulations. But the Executive Order will not be a cure all for the ills of the administrative state, and agencies like DHHS, locked into major legislative implementation tasks, will likely adopt governance changes cautiously and over long periods of time.

Assuming that political capital can be expended on implementing EO 13563 three principles should be adopted in reforming agency governance procedures; they are harmonization, integration and performance based regulation. On an individual basis a given rule may be well-crafted and internally consistent, albeit complex, but the issue arises as to whether that rule can be easily harmonized with other mandates across the spectrum of new and continuing regulations. There is a danger in ACA that the new administrative law it spawns will be highly siloed, resulting in a layering of mandates that become virtually impossible for the regulated to approach in a cohesive fashion. DHHS and the executive branch through OIRA, may have a broader view of regulation but such a vision, as yet, is not appreciated at the level of implementation as providers struggle to meet each mandate as it arises. There is a need in a reformed regulatory system to work toward some cohesion in governance that should begin with an impact assessment that considers how a new set of regulations will be merged with existing obligations, along with consideration of how a given directive will impact the daily operations of regulated parties. Also, regulatory impact evaluations should analyze how a proposed regulation is integrated not only with other federal schemes, but also with state law and private control mechanisms. In turn, authorities, both public and private, should coordinate their efforts, and each new mandate should be seen in reference to the full array of regulations already in place. Where possible current regulatory structures ought to be amended and new frameworks of control should only be developed when use of present schemes is not feasible.

---

67 Id.
Commentators on new governance have noted that regulation is no longer a bifurcated matter separating public and private actors, but rather represents a nodal reality in which various actors interrelate to develop control mechanisms. The existence of diffuse pathways of oversight, mixing together various actors, should be appreciated by traditional regulators, and harnessed in ways to achieve a more workable and cohesive structure of regulation. For example, in the area of patient safety, as noted previously, control mechanisms are being developed by public and private actors alike. Under a nodal view, the network of policy makers, public and private, dealing with safety issues can be joined together to craft operational standards and enforcement mechanisms that exist outside the traditional format of agency rule making. Regulatory processes that combine public and private authorities can be pushed beyond standards setting and be localized into operational models that join providers with government, fashioning integrated responses to legislative initiatives in ways that fit the needs and capabilities of individual markets. In a more fluid system of regulations structures such as Accountable Care Organizations could be guided by general principles, but tailored into distinct and unique systems via active collaborations rather than a massive rule. This targeted approach to regulation would be particularly helpful in areas of implementation based on conceptual models that are evolving, and have yet to be tested fully, even in demonstration project settings. In fact there does appear to be a certain level of

69 Id. at 53.
71 See Burris et al., supra note 68, at 26.
72 The most current example of a conceptual model in health reform is the accountable care organization. There doesn't appear to be a single model which captured the concept, and a series of concepts appear to be evolving as foundation elements to be incorporated in emerging models. See Am. Acad. of Family Med., Joint Principles for Accountable Care Organizations,
flexibility present in ACA that in principle allows for certain innovation and creativity in approaches to crafting reform initiatives.

An applied approach to regulatory reform would be the adoption of contracting principles requiring agencies to fashion control mechanisms, developed specifically for a given regulated entity. In a sense the regulated would be treated akin to contracting parties tasked with achieving certain results. Agencies would have to develop very clear goals about their performance expectations, but such goals could be crafted on an individual basis, and would allow regulated parties to shape their own unique operating policies in meeting government mandates. In addition, a performance specification system could be designed that encourages the regulated to centralize responses in ways that integrate obligations and meet the directives of multiple agencies in a uniform fashion. For example, in areas such as patient safety and quality of care, facilities could develop a collective response to regulatory oversight by designing programs that would be goal driven and in turn, recognized as meeting mandates at all levels of control. In instances where the regulated falters in its tailored obligations, government could be more demanding adhering to a type of responsive regulatory posture, and either specify performance processes or revert to a more wholesale command and control oversight.


73 An interesting example of how contractors are mandated to follow general standards can be seen in the requirements that the Centers for Medicare and Medicaid Services (CMS) must follow in evaluating Medicare Administrative Contractors (MAC). See 42 C.F.R. §§ 421.120, 421.122 (2010).

74 Again, the MAC contracting program can be looked to as a model of using contracting as a level for control, balancing individual requirements, with broad performance specifications. See id. § 421.122(c).

Undoubtedly there are many possibilities for reforming the processes of regulation that could be directed by the broad goals of harmonization, integration and performance specification. Even with liberalization of the attitudes toward regulatory reform in the executive branch, underpinned by a wave of systemic pressures to do so, the task of implementing new regulatory processes will be logistically challenging. The framework of agency governance does change, but significant departures from existing processes occur very slowly and are particularly problematic in the face of ongoing enforcement demands. While political and bureaucratic leaders may endorse process changes, such changes may be hard to filter through massive bureaucracies and may lack broad agency support. In the case of health regulation, changing procedures of governance in ways that empower the regulated will run counter to a very strong strain in the law that has grown over many years which attempts to combat fraud and abuse. There is an increasingly prosecutorial emphasis in health care oversight which runs counter to process reforms, and bespeaks of a lack of trust on the part of regulators posing perhaps the largest hurdle to procedural change. On the other hand, for administrative processes to be revamped in a significant way, those charged with management over the mechanics of regulation must achieve a level of confidence in the new procedures that efficiency in process does not compromise the capacities to address abusive conduct on the part of the regulated.

---


Conclusion

The 2010 federal health reform initiative, combined with the Hi-tech Act and the ongoing juggernaut of health regulation, will have profound effects on all aspects of health care, as it unleashes a massive, costly new set of regulatory controls. In the midst of all this change questions need to be addressed about the soundness of the regulatory processes within which this reform must move. There is growing recognition both within health care, and more broadly across regulated sectors, that current government processes are overly layered, siloed, costly and ultimately inefficient. The recognition encapsulated in EO 13563 demonstrates that awareness of regulatory shortcomings has reached the White House and a template for change has been issued. There are possibilities to revise regulation, embracing the principles noted in EO 13563 by using approaches adopted elsewhere within the framework of a broad regulatory reform movement referred to as new governance. Changes in regulation process will be difficult; in health care such changes will not only make the process more effective but hold the potential to add value to the products produced. The goals of harmonization and integration across regulatory authorities ought to drive health regulatory changes, and although they can be actualized in varying ways, one possibility is the use of performance specifications. Altering administrative procedure will not guarantee the success of health reform, but failure to make changes will be both a lost opportunity and a continuation of an increasingly cumbersome and ineffective administrative status quo.

---

78 See, e.g., Moffit, supra note 41.