

“Exchanging Roles: The Affordable Care Act and New Paths in Health Regulation”

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Crisis and the Challenges of Regulatory Design:

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Argument and Context

The Affordable Care Act, which passed Congress in March 2010, is the most significant health-related legislation to be adopted since Medicare and Medicaid in 1965. It also faces one of the largest implementation challenges—possibly the very greatest—of any U.S. social welfare legislation in the past century.

This is in part because of the law’s scope, in part because of the political opposition that marked the debate over the legislation and that has outlived its passage, and in part because of its potential economic impact. While long bills are not unusual in Washington, legislation that ranges across so many areas of health care is rare—encompassing not only comprehensive insurance reform but health delivery reform and a plethora of issues ranging from posting calorie counts on restaurant menus to granting new funding to community health centers.

Moreover, the legislation is partly composed of numerous smaller pieces of health policy and legislation that have been circulating in Washington for years, sometimes decades. Thus, for instance, the inclusion of a voluntary premium-supported long-term care program, the CLASS Act, inside a bill that otherwise makes relatively few changes either to long-term care or to Medicare other than for financing purposes.

Even with a Democratic president and large Democratic majorities in both houses, passage of the ACA was by no means assured, especially after the early 2010 special election of Scott Brown in Massachusetts eliminated a filibuster-proof Senate majority. Democrats had to resort to an unusual reconciliation strategy which involved the House passing an unchanged Senate bill without resort to committee.

This strategy of necessity had both obvious political implications and consequences for implementation as well. For instance, the lack of a severability clause has made the legal challenges to the ACA more potentially serious. Ambiguity about Medicaid coverage levels prompted the state of Texas to launch a short-lived trial balloon professing a willingness to drop out of the federal program. Scores of polls, including exit polls taken following the November 2010 Congressional elections, show a rough national 50-50 split between opposition and support for the ACA, trending now slightly in favor of support. And the legislation is the only major U.S. social welfare reform (including Social Security, Medicare, and TANF reform) to pass without even a fig leaf of bipartisan support.

The U.S. has been undergoing a simmering health care crisis for several decades. The culprits include poor access to coverage, rapidly escalating costs, uneven quality, unexplained regional variation, and questionable value for money, especially when compared to other countries. Nevertheless, it was surprising that health reform passed in a period of financial crisis. The argument made by Peter Orszag and the Congressional Budget Office about the impact of high health costs on economic competitiveness and long-term debt reduction clearly struck a chord with President Obama. Health care now accounts for almost one-fifth of US GDP and is critical to the functioning of many local and regional economies, such as Pittsburgh, Jacksonville, and Minneapolis. Given the power of the medical industry, much of it opposed to or ambivalent toward reform and wary of its impact in all cases, threading the needle on behalf of reform represented a huge lift, regardless of its clear necessity.

As many commentators have noted, the bill's success or failure depends on how "the regs" are promulgated and interpreted, perhaps more than any bill in recent memory. While most regulation is carried out in comparative obscurity, the ACA regulation, most of it through the Centers for Medicare and Medicaid Services within HHS, has been watched and commented on with unusual intensity both in health industry and policy circles. One would be hard-pressed to find another single piece of legislation that has led to so much rulemaking, and so quickly. The speed and the scope of the regulatory process under the Affordable Care Act, no doubt in part for

political reasons, are unprecedented, according to insiders, and other regulations are languishing to ensure that ACA-related regulation hits the mark.¹

Like most successful legislation, supporters of the ACA relied first and foremost on a “strategy of acceptability,” to use a phrase once rightly applied to the passage of Medicare.² The aims of the ACA, like the regulation which applies it, are nevertheless clear: expanding health insurance coverage, substantially through Medicaid, making this coverage more affordable through bringing down costs, and improving quality of care through a variety of initiatives and demonstrations.³ The goal is to make a version of the protections now embedded in employer-based coverage available to all Americans (except immigrants without legal status). In the apt words of Tom Baker, the Affordable Care Act “embodies a social contract of healthcare solidarity through private ownership, markets, choice, and individual responsibility.” If the expansion of coverage is the heart of reform, then the many efforts to convince the health care industry that going ahead will not be business as usual, especially with respect to costs, are the brains.⁴

While these aims are far from new, the levers that the Act uses to attempt to achieve them diverge from more typical historic patterns of health care regulation.⁵ In its oversight of

¹ I met recently with a lawyer at the FDA who told me that the agency, and other agencies, were meeting deadlines with an uncharacteristic sense of urgency and compromising on thorny issues in order to get the regulations out on schedule. He also described an unusual amount of interagency cooperation but noted that the Centers for Medicare and Medicaid Services (CMS) was writing some rules without consultation even if they turned on things that were best known by members of other agencies, such as Medicaid drug payments. Another senior official at HHS confirmed this basic story.

² The last and perhaps only piece of health legislation which drew praise from all quarters for its adherence to exemplary policy goals and sound fiscal footing was the Medicare Catastrophic Coverage Act of 1988; it was, alas, repealed within one year.

³ See, in particular, Chapin White, “The Health Care Reform Legislation: An Overview,” *The Economist’s Voice*, www.bepress.com/ev, December 2010; Jacob Hacker, “Health-Care Reform 2015,” *DemocracyJournal.org*, Fall 2010; Tom Baker, “Health Insurance, Risk, and Responsibility after the Patient Protection and Affordable Care Act,” Institute for Law and Economics, University of Pennsylvania Law School, <http://ssrn.com/abstract=1759366>.

⁴ To complete the metaphor, the under-the-radar but multi-billion dollar efforts to encourage personal health responsibility toward health through a variety of measures, such as a new council on prevention, are the “limbs.”

⁵ Health regulation of course includes the licensure of drugs, devices, and products, the competence of physicians to practice, and other areas that are beyond the scope of the paper and that are affected lightly by the ACA. Robert Field, *Health Care Regulation in America*, is the best and really the only guide to the history of health care regulation as a whole, though there are excellent studies of individual agencies such as the Food & Drug Administration.

government-funded health programs and of health care financing and reimbursement more generally, Washington has tended to veer between a largely hands-off posture and closely prescriptive federal mandates based on explicit formulae.⁶ Thus, for example, the original Medicare statute explicitly prohibited “interference in the practice of medicine” and promised to pay physicians their “customary and reasonable costs,” leading in part to health care cost inflation and to regulatory capture of the agency by provider groups.

Conversely, Medicare hospital reimbursement reform in the early 1980s specified precise values for 540 diagnosis-related groups that apply differently to each hospital in each region of the country. Certificate of Need (CON) legislation in the 1970s was similarly prescriptive. Medicaid uses a strict federal match rate that varies by state and mandates benefit coverage but gives states tremendous latitude in practice over which benefits to cover and at which levels of reimbursement, despite frequent state complaints on this score. This general picture of lofty federal distance or micro-management of reimbursement is borne out by just about every piece of health legislation since the 1960s.

It is too early to tell for certain in which ways the ACA will fit or break this pattern. However, the legislation makes a telling set of choices that seem to put it on a new and distinctive regulatory path, at least within the realm of health policy. (By regulation I mean here, and throughout, the prescriptive elements that are contained in the statute as well as the ways that they are converted into administrative law through the actual regulatory process.)

In sum, the emphasis is on cooperation and voluntary partnership between the federal government and insurers, government and individuals, government and physicians, and the government and states, rather than employing rate regulation or the simple devolution of regulatory tasks. Again, this choice was of course in large measure dictated by political reality: the setting of drug prices, the phase-out of the private insurance industry, or a “base closing” approach to underperforming hospitals would have been fiercely opposed by industry and others and almost certainly prevented passage of the ACA. This would have been true even if overall

⁶ Of course this hands-off policy was in pursuit of universal ends, so that the states or insurance carriers were used more as subcontractors than as partners in implemented legislation, as in Medicare. It is possible to go from more federal hands-on to more distant and devolved, as in the 1996 passage of welfare reform. The point is that true state-federal partnership is rare while the hand-off of costs and duties is more commonplace.

public opinion, which was equivocal, had been solidly behind a single-payer reform or the public option.

Nevertheless, it is worth looking more closely at the choices made in three areas of regulation where cooperation and partnership seem to have been actively sought rather than principally dictated by political expedience: insurance regulation and the individual mandate; Accountable Care Organizations (ACOs); and the creation of state-based insurance exchanges. These areas, in particular, attempt to use private entities for public purposes in ways consistent with (and perhaps directly influenced by) trends in regulation marked out by the Tobin Project and others.

Insurance Regulation and the Individual Mandate

Insurance market reform is the most conventional form of regulation included in the ACA. This includes requirements that Americans up to the age of 26 and not covered by other insurance be able to stay on their parents' insurance policies⁷, guaranteed issue regardless of pre-existing conditions, medical loss ratio requirements, and transparency and justification for insurers' premium increases.

The centerpiece of the insurance reforms, however, is the individual mandate: the requirement for all Americans to purchase insurance coverage unless exempted for reasons of low income or religious conviction. Leaving aside the constitutionality of the mandate⁸ and looking solely at its practicality, it is the only way to achieve near-universal coverage in the absence of a government-run single payer system--while leaving the private insurance industry, along with the existing marketplace for medical care, largely intact.⁹

⁷ In fact, there has been robust take-up by younger Americans of this policy.

⁸ Two of the most concise and thoughtful pro and con views are Mark A. Hall, "Is it Unconstitutional to Mandate Health Insurance?", www.healthreformwatch.com, August 25, 2009, and David B. Rivkin Jr. and Lee A. Casey, "Illegal Health Reform," *Washington Post*, August 22, 2009.

⁹ The individual mandate was the centerpiece of the 2006 Massachusetts universal coverage law, which has led to reduced premiums for unsubsidized policies and near elimination of uninsurance, although the take-up for the unsubsidized population in the state has been less than expected.

Without a mandate and with restrictions on insurers, a “death spiral” based on adverse selection is both a theoretical and a practical likelihood.¹⁰ To be sure, there are ways to induce higher enrollment in the absence of a mandate, such as opt-out clauses with a significant penalty for re-entering, as in Medicare Part B, or tight open enrollment periods. But these expedients would result in at best two-thirds of the take-up of a mandate, leave out the youngest and healthiest Americans who are most desirable in an expanded risk pool, and result in higher government costs through subsidies for lower coverage rates.¹¹

Politically, the individual mandate was a *quid pro quo* for large insurers. Including it was the only way to ensure that the most influential companies, and their major trade association, either backed the reforms or, for the most part, stayed on the fence. (One relevant contrast, both structurally and politically, is with the Clinton Plan, which would have regulated premium increases by insurers.) Taken as a whole, however, the insurance regulations are consistent with the standard pattern of US regulation in which raising demands on the private sector is viewed as a desirable alternative to higher levels of public spending or public ownership.¹²

From a regulatory standpoint, what is unique about the individual mandate is perhaps less its impact on insurers than on the expectations it makes on individuals as purchasers. Again leaving aside whether it is permissible to compel individuals to buy private insurance coverage, it is hard to think of another policy, apart from conscription for military service, in which the action or inaction of individuals will play such a large role in a policy’s success or failure. (To be sure, many government programs suffer from lower enrollment than eligibility for them would suggest. However, this is generally because of lack of knowledge, inertia, or inconvenience on the part of beneficiaries. Rejecting the mandate will involve a more active opt-out instead of a passive failure to enroll.)

Many have pointed out that the penalties for non-compliance with the mandate are weak (and similarly lenient for large employers who fail to meet the requirement for covering their employees) and point to this as a fatal flaw in the policy.

¹⁰ Jeffrey Clemens, “Regulatory Redistribution in the Market for Health Insurance,” <http://www.people.fas.harvard.edu/~clemens/papers.html>.

¹¹ Jonathan Gruber, “Health Care Reform Without the Individual Mandate,” Center for American Progress, February 9, 2011.

¹² *Oxford Companion to Law*, 692.

By contrast—and here I rely in part on personal conversations with a number of the relevant policymakers—this can be viewed not as a flaw but as a design feature. The overwhelming belief among backers of an individual mandate is that if persuasion is insufficient, compulsion is unlikely to succeed. The penalties, in this view, are deliberately low because they are designed to nudge citizens into acting in their own and in society’s best interest rather than being harshly punitive. While some find this concept of a “culture of health coverage” naïve, it has close parallels to studies of tax policy which find that people pay taxes largely because of cultural norms and peer pressure rather than because of fear of being caught for evasion.¹³

Establishing and Regulating “Accountable Care Organizations” to Reduce Costs

Regulation, custom, and professional self-interest kept doctors and hospitals at arm’s length for most of the twentieth century. Doctors kept admitting privileges at hospitals and used their facilities but were paid separately and directly by insurers, while most hospitals did not have physicians on the payroll. Staff model managed care plans such as Kaiser Permanente and a few others, mostly on the West coast, were the exception rather than the rule.

This distance is being steadily lessened both in practice and in law, in part because of the decline in numbers and prestige of primary care physicians and the need for doctors who managed patient flow and care in the hospital and the emergency room. So-called “hospitalists,” who work directly for hospitals and draw a salary, are one of the fastest growing areas in the physician workforce. Much of the stigma attached to permanent hospital work is rapidly dissipating in the medical profession.

The Affordable Care Act builds on this trend of tighter actual and legal co-operation between doctors and hospitals by encouraging the creation of Accountable Care Organizations (ACOs). Conceptually, these are groups of providers—physicians or other clinicians, hospitals, and clinics—who will band together as a corporate entity, conforming to state law, to provide

¹³ For instance, among many, <http://www.becker-posner-blog.com/2007/11/why-so-little-tax-evasion-becker.html>, but there are many competing theories, not all incompatible, including the possibility that people overrate the chance of being audited.

care for a designated group of patients. Under the statute each of these entities must have a minimum number of primary care providers in their networks.¹⁴

The expectation of policymakers is that these groups will coordinate care more effectively and “share savings” relative to the benchmark cost of their patient group. The hope is that by introducing a bonus for saving money while meeting a bevy of quality standards doctors will cut down on now-wasted or superfluous care and encourage the right procedures to be done in the right settings. These were, of course, the original goals behind managed care. The expectation is that with doctors and hospitals in the driver’s seat the changes in care delivery will be palatable to (and in most cases largely invisible to) patients and the public.

ACOs are the flagship for many of the other ACA provisions designed to bring down the growth in health costs—including the Center for Medicare Innovation and a new federal entity designed to compare the effectiveness of medical treatments. They are intended to bring the coordination and efficiency association with integrated systems and HMOs while maintaining a much looser governance structure than these systems. Most health economists peg fee-for-service payment, which encourages a high volume of procedures, as a major factor behind rising health costs. By starting with Medicare fee-for-service beneficiaries, ACOs will potentially act as an entering wedge to help bring down health spending. Policymakers expect, as well, that what is begun in Medicare will be adopted in employer-based insurance markets, as has occurred in multiple previous cases.

From a regulatory perspective, Accountable Care Organizations are striking in a couple of ways. First, they are in effect a completely novel form of health delivery organization, though plans that delegate risk to medical groups in California are a reasonable facsimile. (Health policy types frequently compare ACOs to unicorns-- something which hasn’t been seen but everyone can recognize. They might also be compared to California condors, rare and seldom found except in tightly-regulated captivity.) That the entity was created by the ACA and defined loosely in the original statute was a political asset; it was and to some extent remains a useful vehicle for all comers in the industry to project their hopes on.

¹⁴ Probably the single best explanation is “Accountable Care Organizations,” Health Policy Brief, *Health Affairs*, July 27, 2010.

Second, ACOs reflect the overriding philosophy of the legislation in using markets and economic incentives to accomplish a reduction in the growth of health costs rather than through explicit rate setting, the direct regulation of insurance premiums, or the imposition of caps on health budgets. These latter methods are used in other countries and in Medicare to considerable effect, as well as in the all-payer hospital rates still in use in Maryland.

To reach this end, the ACO idea envisions not only a much closer co-operation than ever between hospitals and other providers but greater than normal co-operation between the federal government, states and providers as well.

Just how far-reaching this arrangement would be was illustrated during the release of the much-awaited interim regulation on March 31st of this year. While expanding the range of providers who could participate, federal regulators proposed stringent financial disclosure and transparency rules, insisted upon federal review of marketing materials, and mandated that new ACOs report on sixty-five different health process and outcomes measures.

The industry responded with the sound of one hand clapping. They balked at the financial disclosure and marketing rules, the network requirements, the “laughably prescriptive” reporting rules, and fretted that there would be little opportunity to receive shared savings even if they followed all the rules. They also pointed out that the ten-site pilot on which the ACO concept was field-tested included mostly integrated delivery systems with much more experience and with a uniform set of electronic health records in place. Those potential hospital-physician networks inclined to take the plunge want to take on full risk and receive higher per person (capitated) rates and those that are on the fence—the most important given the aims of policy—are unlikely to be tempted because of the high upfront costs and the uncertainty of seeing substantial payoffs in a short timeframe.

As health consultant and former CMS official Ron Klar put it, “The proposed rule creates a program that is likely to have few participants. This is because it is overloaded with provisions to mitigate the likelihood that any conceivable negative possibility will occur, rather than trusting the design and encouraging and supporting participation.”¹⁵

¹⁵ *Health Affairs*, April 7, 2011.

Some continued to worry about running afoul of antitrust law; the FTC issued a short companion advisory explaining which levels of market share might constitute a “danger zone.” This, however, has satisfied few within the industry.

While many of these criticisms appear sound, the main point here is not necessarily their rightness or wrongness but the evidence of the symbiotic relationship between hospitals, doctors, and the federal government in the regulatory process. While businesses are always keenly interested in how their industries will be affected and the regulatory process is always one of give and take, it is instructive how much the carrying-out of a broader public policy—the slowing of the growth of health care costs—has been delegated in effect to private entities. Following the negative response to the initial regulations, the Obama administration released a new set of options designed to try to bring back major health systems to the fold, including expedited certification and help with start-up costs.¹⁶

The irony, perhaps, is that this courtship may be misplaced. ACOs that are big enough to gain efficiencies are also likely to be large enough for their dominant hospitals in the network to take back with one hand what they give with the other—through capturing higher rates from insurers due to their local market power. Costs, in short, may not come down. More flexibility and genuine competition might emerge from regulating hospital prices more tightly, as is done in most European countries, rather than by using market incentives to attempt to achieve public-minded ends such as health cost containment.¹⁷

State-Based Benefit Exchanges

In a speech to the National Governor’s Association earlier this year, President Obama laid down a marker by saying, in effect, that if states could achieve the goals of the ACA by other means, and in particular the expansion of insurance coverage, more power to them.¹⁸

¹⁶ Jenny Gold, Kaiser Health News, “Administration Offers New Path for ACOs” May 17, 2011.

¹⁷ Zachary N. Cooper, “Competition in Health Care Markets Requires More Regulation, Not Less,” *Altarum.org*, December 16, 2010.

¹⁸ Kevin Sack and Sheryl Gay Stolberg, “Obama Willing to Give States Break on Health Care Overhaul,” *New York Times*, March 1, 2011.

At the time this was taken as a sign of political weakness, an olive branch to the newly-elected governors, many of them Republican, and a possible retreat from the original goals of the ACA. But if one looks at the central role of health insurance exchanges in the law, and in the states' role in creating them and administering them, Obama's nod to federalism seems less out of place.

Health insurance exchanges are new mechanisms for helping consumers and small business shop for coverage in a way that allows easy comparison of available plan options based on price, benefits, and quality. This ability to compare plans is vital for individuals and small businesses who buy coverage on their own. Under the statute, each state (or combination of states) must build their own exchange by January 2014 or the federal government will step in to do the task for them.¹⁹

Because exchanges will be the portal through which billions of dollars in federal subsidies will be made available to purchase health insurance for middle-class Americans, subsidies which will also flow to most of the country's medical providers, it may well be the single most important element in whether the ACA ultimately succeeds or founders. And most of the key decisions have been left in the hands of states, which have been given tremendous leeway in determining what their exchanges will look like.

This latitude is not unbounded, however. It takes place within a "menu" of options laid out in the federal statute, including whether the governance of the exchange will be non-profit, an independent public authority, or an existing agency; whether there will be separate exchanges for individuals and small businesses; whether insurance plans can offer the same products inside and outside the exchange; and whether the exchange must be a clearinghouse for all comers or if it can select specific insurers based on consistent standards. While HHS has offered guidance on exchanges, it has not completed the full regulatory process for exchanges, including specifying which "essential benefits" will need to be included in each tier of coverage.

The hybrid roles that exchanges are expected to take on mark them as something unusual not only in health care but in U.S. social policy more generally. As one analyst points out,

¹⁹ As of this writing, Louisiana and Florida are the two states which have opted out of creating state-level exchanges and have returned the federal money designated for that purpose.

exchanges will be the “distribution channel for commercial insurance, the conduit for premium subsidies and reduced cost-sharing, and [the] enforcement arm for compliance with the individual mandate.”²⁰ It’s hard to think of a parallel at the state level of a new entity carrying out federal policy goals. Generally speaking these entities are either more autonomous (like Arizona’s Medicaid program) or seek permission from the federal government to establish their own programs using federal dollars (as, for instance, California’s recent renewal of its hospital waiver). While the federal government is backstopping state exchanges with money, demonstration projects (Early Innovators) for exchanges that adopt use technology in forward-thinking ways, and ramped-up regional HHS offices, the fact remains that states will be the principal arbiter of whether exchanges are up and running, and whether they will stand or fall.

One of the most salient decisions left up to states, in fact, is whether the exchange will become a de facto regulator by structuring their exchanges as either “passive” or “active.” A passive exchange is a centralized place where people can learn about coverage options and all plans that pass the minimum standards for certification under the ACA can be accessed through the exchange. The Utah Health Information Network is a pre-health reform example of this passive kind, though it is likely to pass muster under the new exchange rules. In an active model, the individual and small group purchasing pools will negotiate separately or collectively with insurance plans and work with these carriers to design products that are appealing to enrollees or that promote strategies for combatting chronic illness. They may also contract selectively to exclude insurers who are unwilling to offer such products. The state of California, which was the first to design an exchange in response to the provisions of the ACA, opted strongly for the active purchasing model. However, states with fewer insurance options and fewer lives covered on the exchange might find the active model backfiring, since it may be unable to bargain with insurers for higher standards. In either case, the law allows unusual flexibility for states to use the reforms to reshape the way health care is delivered.²¹

Conclusion

²⁰ Robert Carey, “Health Insurance Exchanges: Key Issues for State Implementation,” AcademyHealth, September 2010.

²¹ See Timothy Stoltzfus Jost, “Health Insurance Exchanges and the Affordable Care Act: Eight Difficult Issues,” The Commonwealth Fund, February 2011, and Micah Weinberg and Leif Wellington Haase, “State-Based Coverage Solutions: The California Health Benefit Exchange,” The Commonwealth Fund, May 2011.

The progress of health regulation bears a strong resemblance, if not debt to, what John Braithwaite has termed regulatory capitalism, the expansion of regulatory agencies which delegate their power to corporations, state agencies, and newly-formed public-private partnerships.²² Health regulation formerly was prescriptive with respect to rules and reimbursement policies but now has moved into the realm, however tentatively, of social behavior. Like most pieces of passed legislation, the design of the Affordable Care Act represented a solution both to a political problem and to a policy problem. In its implementation, however, it may be charting new regulatory paths.

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²² John Braithwaite, *Regulatory Capitalism: How It Works, Ideas For Making It Work Better* (Cheltenham: Edward Elgar, 2008).