

Legal and Regulatory Workshop
Rapporteur Notes-by Paul Vronsky
Nov 29-30, 2007

Roger Noll

- What role can regulation play in solving healthcare problems?
- Regulation per se cannot be relied upon, need to rely upon institutions that are going to be implementing health care reform
- Regulation is costly and anti-competitive
- If you don't like competition → single payer
- If you like competition → don't regulate because you destroy the good features of competition
- Regulation is not a particularly good way of dealing with healthcare problems
- But it will likely be a necessary component of any reform
 - Reason for this is politics
- Three models
 - Direct public provision
 - Procurement model
 - Subsidization of individuals
- Use regulation *per se* to address particular problems
- Regulation defined – admin process for controlling transaction or production activities in which the government is not itself the buyer or seller
- Why regulation is procedurally freighted?
 - Rules emanating from bureaucracies are looked upon by lawyers as less legitimate because of the lack of democratic involvement
 - Agencies are held to a higher standard in their rulemaking
 - Risk of loss of control for those who delegated authority
 - Don't use budgetary process to control
 - Need to control procedures by which regulator works
- Natural alliance between providers and people
 - Regulatory institutions will accord great weight to providers and thereby be anti-competitive and not affect behaviors/norms which drive costs
- Purely regulatory approach to deal with incomplete coverage is universal service (akin to public utilities), cross-subsidize
 - This is the instrument of choice for achieving universal service
- Problems in healthcare relative to cross-subsidization
 - Narrow tax base for generating the revenues necessary for the subsidy
 - More anti-competitive than regulation; has to be in order to prevent skimming

Rep. Jim Cooper

- Overall tone of pessimism is maybe not necessary
- Hospitals are preparing for fiscal crisis and necessary change
- Physicians aren't as prepared but do see things on the horizon
- Haven't tried educating consumers as to where quality providers are

- New paradigms are possible
- We won't succeed second guessing physicians, have to train people to do it right the first time
- Need to get doctors to think like airline pilots

Gillian Hadfield

- She takes Roger's point to be that regulation is an external constraint on markets that is captured, complex, and costly
- Bottom line from the paper: inefficient regulatory system won't fix inefficient healthcare system
- Any market based component will require civil litigation structure
 - Contracts/entitlements → dispute resolution
 - This leads to problems that are inherent in the legal system
 - Cost, delay, competence, bias, accessibility
- Legal/regulatory component unavoidable
- Can't fix healthcare system with a broken legal system

Mark Hall

- Legal process approach
- In addition to substantive rights, need to address process rights
- It is about institutional particulars
- Certificate of Need laws have not been demonstrated to be a significant barrier to entry
 - Incomplete
 - Entry controls but no pricing controls, luckily entry controls don't work
- FDA is a good thing and a good example of an institution that works

Bill Sage

- Need to address collective welfare and not individual cases
- Need to draw the traditional healthcare and public health together
- What kinds of administrative agencies can we create?
- Can we change Medicare from a payment system to a collective agencies
- FDA struggles between protecting people and giving access
- Need to address state/federal issues
- Start with a payment agency and move to a regulatory regime
- Start with an agency that is established and move it to the health care area

Discussion

- Regulation – generally
 - Distinguish between regulation for efficiency and regulation for redistribution
 - We're not going to get healthcare reform without redistribution, and we'll want efficiency
 - Healthcare captures the point that you shouldn't separate efficiency/redistribution
 - Lack of trust in the government

- Expanding bureaucracy isn't the answer, you may need a new bureaucracy
 - Need competition on quality and not risk
- Regulation – constitutional issues
 - Inducing states by means of funding is easier than regulation (spending clause)
 - Feds have more leverage
 - Federalism
 - Set a basic national standard (HIPPA) and then let states tailor the plans to themselves
 - Have broad universal standards but technical variation as is appropriate for a given area
 - This is also how Medicaid works
 - Offers a model that works well in the country
 - You have the ability to experiment
 - The alternative of a national system focuses the political pressure on one decision maker
 - Federalism is a big issue in the current mess with health care
 - Two sovereigns trying to deal with the same problem
 - Federalism is often used as a political tool to implement but nothing substantive
- Involvement of government in healthcare system
 - Traditional legislation has a lot of costs that it imposes
 - There is a role for government, but not regulation
 - Information provision to the private sector
 - Need to take a functional approach
 - There is no way of getting a regulatory structure, irrespective of competitiveness
 - Must take into account admin/legal costs
 - Simplicity will be less expensive
- Legal system
 - Laws are complex because that is how society is generally
 - Interest groups
 - Question of special interests among providers: is this a systemic problem or simply special interest politics?
 - ERISA and external review processes have shown how the legal system can evolve to deal with particular issues and settle in relative equipoise
 - Create an administrative law substitute for the regular legal framework to certain entities (parallel to some proposals for medmal)
 - If you have a narrow range of offerings in benefits, you have less litigation
 - Conduct of the healthcare issues raises legal issues
 - Incoherence of the system drives this
 - There is very little innovative in legal arena that will help healthcare
 - There are barriers to entry
 - There is nothing in the current legal institutions to optimize the level of complexity in the system
 - There is too much law

- There isn't too much law, we don't use it well
- There isn't much litigation in healthcare
- Need to account for regulation through settlement
 - Major shifts in behavior due to settlements
 - False Claims Act
- The legal problems in healthcare is in the transactional work done by lawyers
- HIPPA is being used by lawyers for docs in medmal to withhold information
- Discrimination
 - Need a toolbox to address discrimination in healthcare provision after solving healthcare access issue
 - Mutual of Omaha case from 7th Circuit
- Regulation and innovation
 - Controlling innovation is wrongheaded, maybe need to control access to innovation
 - Regulate innovation types not quantity
 - The legal/regulatory issues here are the same as they are in the general healthcare structure problem already discussed
 - Could create a government agency that assesses technology
 - Legal issue of the patent system and monopoly power
 - How drug companies pay docs is problematic
 - Problem for innovation is the delivery system and not so much patent system
 - Process patents impossible in medicine but need subsidy to address public good problem
- Healthcare investments
 - Investment in healthcare has limited returns
 - How can law/regulation increase these returns?
 - What tools do you use?
- Transparency
 - This is a second order issue that is subsumed by the general idea of healthcare
- Implementation of healthcare system change
 - How?
 - Move to the intersection of legal and political
 - ADA is a big impediment to some of the implementation
 - Other facets of current regulatory scheme?
 - What needs to be changed?
 - We need to take away laws and not just layer on the existing sediment
 - Developing a better accounting system for healthcare
 - Need to get a better grasp of cross subsidization
- Corporate practice of medicine doctrine
 - State case law
 - Can't be employees
 - Organizations that want to can surmount this difficulty

- Implementation through legal systems
 - Lawyers: give us your ideas and we'll figure out what the legal problems are
 - Bring lawyers in early
 - Two stages to translate an idea into a legal framework
 - Detailed set of specifications of what will need to change where
 - Translation into legal jargon
 - Manitoba example 26 pages of health law
 - Clinton proposal was over 1000 pages, with half of it being the meat of the proposals
 - The ability to recoup lawyers fees creates an incentive to sue for lawyers
 - If we write something detailed, courts can't gap fill
 - Lots of good statutes are broad (Anti-Trust), specificity has downsides
- Medicare
 - Incentives in Medicare are misaligned
 - Medicare is skewed against primary care
 - AMA specialist capture of Medicare is driving payment schemes' problems
 - History of Medicare is rife with politics
 - Issue of CMS becoming more of a regulatory agency
 - Where does payment end and regulation begin?
 - Big legal question of Medicare Part D and bringing price discipline into that area
 - Local variation is often a reason for Medicare issues
- Canada
 - Has much less private litigation
 - The US does a lot of private litigation
- Germany
 - Comprehensive care required and costs can't rise faster than inflation
 - But government stays out otherwise
 - Very legalistic, specialized courts, etc.

Jost Presentation

- Functions of Law
 - Creator reflects/establishes principles, institutions, procedures and policies
- Law reform needs to address these four areas
- Forms of law
 - Command and control, criminal, licensure, rules governing coverage and payment, private groups regulating, federal/state tax subsidies, private law (contract/tort), constitutional law
- Major Issues
 - Federal state relations
 - Entitlements to health care
 - Markets for insurance

- Markets for health care products and services
- Federalism
 - Constitutionally, the states are responsible for the public health and welfare
 - But federal powers under commerce and spending are broad
 - Medicare is simple, Medicaid more problematic, ERISA is exceedingly complicated
 - Approach
 - Favors a federal entitlement to healthcare
 - Allow 3 or more states to opt for higher protections
- Entitlement
 - Medicare and the employee benefit tax subsidy are federal entitlements
 - Medicaid and ERISA offer more limited entitlements
 - Federal law imposes few mandates
 - State law imposes many mandates
 - Recommendation
 - Entitlement established by federal law
 - Protected by administrative review (judicial review on deferential basis)
 - Commission to determine coverage
 - Things that must be covered
 - Things that cannot be covered at public expense
 - Optional coverage
 - Coverage recommended but not required
- Regulation of insurance markets
 - Federal tax subsidies, COBRA, HIPAA
 - State small group and individual market underwriting
 - Recommendation
 - Difficult to make private insurers act like social insurers
 - Individual mandates and subsidies needed if no public insurance
 - Risk adjust subsidies
 - A public insurer might be useful
 - Government could provide reinsurance
- Regulation of Markets for Health Care Products and Services
 - State licensure and certificate of need laws
 - Federal antitrust laws
 - Federal bribe and kickback, self-referral, and inducement to limit service prohibitions
 - Recommendation
 - Encourage coordinated and efficient care delivery
 - More rigorous antitrust enforcement
 - Prohibit referrals for remuneration
 - Statutory exception
 - Allow relationships that serve another purpose
 - Permit gain-sharing with safeguards
- Malpractice?

- Others know more and this isn't an issue
- Health care distribution parallels income distribution
- Need to move money from rich to poor to cover
- Netherlands has a system where 60% of public receives health insurance subsidy
- In order to control healthcare costs will mean moving individuals in the medical profession down the income distribution curve (pay providers less)

Bill Sage

- Tim is right and detailed
- Don't get lost in the details
- Doesn't think that you can get close to health care reform if you don't bring it closer to public health system
- It is all about delivery
- All the law that we have is generated by healthcare providers
 - Professionals and professional organizations and customs are in control
- Fiscalization of collective meaning
 - Medicare is an example
- Need collective meaning in healthcare provision
 - Accountability centers could provide that
 - One stop shops
- Anti-trust operates in healthcare because of Medicare
 - The competition is layered on top of a major payment structure
- Need to provide a financial cushion to allow providers to experiment in delivery
- Medicaid provides good examples
- ERISA
 - We have given businesses great freedom to control healthcare provision
- Doesn't think that investments in healthcare shouldn't be tax deductible

Mark Hall

- Constitutional issues
- In many ways the law is obstructive to well informed policies
- Canadian con law case
 - A doctor sued over the ban on private insurance, Canadian Supreme Court found this to violate Quebec Charter of Rights
 - Similar to heightened scrutiny analysis in the US
- Abigail Burrows in DC Circuit
 - Father brought suit over the fact that daughter couldn't obtain the only treatment available because of FDA rules
 - Panel found the rules violate individual rights
 - This was reversed on appeal to en banc
- These rulings probably wouldn't happen on a broad basis in the US because of how healthcare rights are interpreted
- There has been resistance to constitutionalizing things within healthcare
- State courts could develop a more stringent constitutional review
 - This feeds into federalism issues
 - Want to have federal authorization to deal with this

Gillian Hadfield

- Complex legal environment
 - The US relies much more on private enforcement (litigation) than other countries
- There is a strong tendency on talking about legal problems as policy problems
 - Important distinction
- Law is costly (time, diversions, money)
- It is organic
 - It doesn't stay there after you write it down
- Law on the books doesn't equal outcomes
- Legal reform requires institutional innovation
 - Private, competitive dispute resolution/law providers?
 - "Health" courts?

Rep. Cooper

- Dead hand of consent decrees
 - A form of law that is forgotten about
- Need more of an engineering mindset
 - No relationship between design and responsibility of design
 - Lawyers are part of the problem
- Rights fetishism
- Entitlements are fictions
 - Accounting of future costs is not happening
- Focus on retail aspect of medicine
- Plural of anecdote shouldn't be a policy
- ERISA is a mess

Discussion

- Misperceptions in Healthcare
 - Lifetime and not annual is the proper time frame in healthcare
 - Human capital is a large part of wealth, just looking at income distributions is deceptive; should look to wealth distributions including human capital, they are different
 - Managed care cost controls during the 1990s worked
- Constitutionality – generally
 - Health law is basically a constitutional free zone
 - This could change at some point though (forcing states to do things, also due process concerns)
- Federalism
 - Federalism restricts commandeering
 - Preemption question is settled easily by law, that is not commandeering
 - Licensure is a good example, probably the furthest feds could go with commandeering
 - Law is not necessarily the problem, it is how it is used
 - The reality is that the commerce clause argument is dicey

- Example of eye glass cases
 - State implementation of welfare programs is driven by the politics of the time
 - Only areas where this isn't the case is EITC and SS, where the government just sends a check
- Legal means
 - Tradeoff between admin law and contract
 - Pure contract enforcement could be costly
 - Alternative dispute resolution is important
- State laws
 - A lot of impediments exist at the state level
 - Innovation is restricted by state laws, this will require preemption
 - Problem of risk taking by small for-profit and large non-profit providers in a friction filled environment makes it hard to innovate
 - Medicare has a difficult time with innovation and demonstration projects
 - You can't tell states what they do with their practice of medicine laws (you run into federalism issues) but you can provide financial incentives to do that (federal spending powers)
 - This is a political issue, not necessarily a constitutional one
 - There needs to be room for states to innovate
 - New England tried to come together to set common rules on licensing
 - It was hard to do, interstate compacts are difficult to get → get feds to do it
- Preemption
 - There is a spectrum of preemption
 - ERISA is an example is where the feds take the field entirely (rare)
 - There are more examples of cost sharing and sharing the regulatory field
 - Solution could be a federal establishment of a right, but a shared responsibility of execution
- Anti-trust
 - The law will look at actual mergers versus quasi mergers differently
 - There actually has been a lot regulatory successes stopping med mergers (docs and some hospitals)
 - Vertical integrations are possible
 - Hill Physician example (3000 physicians), are there legal impediments?
 - Economies of scale
 - Placement
 - Selective in who they allow into their operation
 - They pay specialists not based on procedures
 - What are the legal responses?
 - Stark Law has a very narrow definition of a group practice, if you don't meet that you have problems with referrals for ancillary services
 - The legal problems aren't facially apparent
 - The other issue is Medicare reimbursement

- This suggests a problem because each individual group has to be examined
 - Set up safe harbors
 - But doesn't that ossify and eliminate the innovation
- Set up the legal parameters
- There needs to be guidance with respect to anti-trust issues
- Fraud and abuse laws
 - Stand in the way of integration in healthcare
 - Fraud and abuse laws are a project in and of itself
 - You can set up the safe harbors for fraud and abuse really quickly
 - You can create a defense if you save costs or improve quality
 - Burden of proof point
 - If it is on the defendant then there could be problems
 - Advisory opinion process is broken
 - Challenge the premise for restrictions on organizing
 - The problem is kickback fraud (not fraudulent billing)
 - This is amplified by the False Claims Act and a whistleblower who raises a claim that is really frivolous
 - Results should matter more than the few occurrences of fraud
 - Don't need to worry about anti-trust, get rid of fraud and abuse law problems in a discrete fashion
 - Reasonable to revisit fraud and abuse laws in Congress
 - In order to be accessible to Congress, the idea needs to be presented "in one page"
 - Idea has to be for the common good
 - Need the Institute of Medicine to take a look at Stark Law and the fraud and abuse law
 - Need to look at tax exemption as well in medicine
 - Thus far all that has been done is a revision of the tax process
- Insurance
 - Discussion of insurance laws and how they are regulated within the states, similar path to reform as the discussion on general healthcare reforms
 - Difficulties in selling insurance across state lines
 - Self-insurance is very widespread among 200+ employee companies
 - There are a lot of small players in the small insurance field though
 - Maybe there ought to be a national charter for insurance
 - Real issue with state regulation of insurance is the race to the bottom
 - Healthcare finance is too big of a problem to deal with on 50 state basis
 - Getting rid of state insurance regulation is looking at the problem the wrong way
- Law and economics
 - Need to get economics into medical care, it isn't all science
 - The law can recognize the economic dimensions of healthcare provisions
 - Don't want economics to corrupt medicine either
 - Have to be restraints on procedural processes in medicine
 - Triggering a review process can't be too costly

- Get rid of the term “medical necessity”
- Need a subtractive process in the legal changes