Is Health Law the Enemy of Health?

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The Two Warring Stories Behind Health Care Law

- Good doctors know what they’re doing: Just trust them. Law should intervene only when doctors fall short of standards set by the “good docs”
- Doctors are as venal as the rest of us – and too often paternalistic. They need to be pushed toward good behavior.

Good Doctors Know What They're Doing

Medical law's classic model

- Tort Law: Deference to physician-set standards of care in med-mal cases.
- Legal safeguards for professional autonomy (e.g. rule against "corporate practice of medicine).
- State licensing standards set and enforced by boards of practicing physicians.
- Little to no role for competition: Immunity from anti-trust regulation until the late 1970s.

Doctors are as venal as the rest of us

Left-Leaning Version of the Story:

- Informed consent as a safeguard against paternalism.
- Regulatory approaches to quality and cost: E.g., health planning & C.O.N. regulation; anti-kickback rules and restrictions on self-referral; mandatory peer review; more robust professional discipline

Doctors are as venal as the rest of us

Right-Leaning Version of the Story – Competition:

- From informed consent to consumer choice.
- Competition between integrated health plans.
- Competition between providers – doctors and hospitals.
- Cost-sharing to motivate consumers: Premiums, deductibles, & copayments.

The Competition Story: Legal Implications

Empower entrepreneurs & create incentives:

- Robust application of anti-trust laws.
- End to health planning & C.O.N. regulation.
- Roll-back of restrictions on kick-backs and self-referral.
- End to regulatory safeguards for professional autonomy.
- Roll-back of tax subsidies for purchase of health insurance.
- Ability to contract for standards of care lower (or higher) than those set by medical malpractice law
- Roll-back (or ERISA pre-emption) of state coverage mandates (e.g. minimum benefit & “any willing provider” laws).

The Scope of the Anti-trust Agenda

- Uncontroversial: No collectively-set restraints on price competition or advertising.
- More Controversial: Physicians can't collaborate in the marketplace to oppose particular incentive arrangements – e.g., rewards for providing less care (problematic if one hews to the Hippocratic ideal of undivided loyalty to patients)
- Good News: FTC & DoJ Anti-trust policy promises safe harbor for collaboration aimed at improving health care quality (e.g., development and implementation of evidence-based practice protocols & P4P schemes).
- Dismaying to doctors & hospitals: Anti-trust agencies look askance at collaboration that raises prices, even if this collaboration promises quality-enhancing clinical integration.

Law versus Reality

These several approaches to health care law share two unrealized assumptions:

- Existence of a comprehensive body of knowledge about the effectiveness of clinical interventions
- Widespread agreement on how to *value* clinical benefits (& weigh them against costs) when we're *able* to measure effectiveness.

Law versus Reality

If these assumptions were accurate:

- The “good doctors know what they’re doing” model could make sense: There’d be a “right” way to practice medicine (though free marketeers might quibble over the profession’s cost-benefit trade-offs)
- The “doctors are as venal as the rest of us” model could make sense: Regulators could impose the “right” resource allocations and practice protocols (subject to quibbles over “one-size-fits-all” cost-benefit trade-offs). Or health plans & providers could market competing menus of cost-benefit trade-off options.

Law versus Reality

- But as we all know now (thanks to John Wennberg & many others), these assumptions aren't accurate. And different doctors handle like scenarios in astonishingly different ways.
- We're nowhere near to either a comprehensive body of clinical outcomes data or consensus on how to value outcomes.
- So there's huge indeterminacy, and room for conflict, over legal & regulatory questions about the right treatment, the right resource allocations, and the right competition policy.

It gets worse ...

- Health care law is created by a chaotic patchwork of decisionmakers, in 60 plus jurisdictions (50 states plus 12 federal circuits)
- Scores of state & federal agencies; 50 state legislatures in addition to Congress, with its multiple committees & overlapping jurisdictions.
- The result: guaranteed incoherence as these multiple actors push in different directions

And worse ...

- Indeterminacy & incoherence create space for health care’s many, well-financed interest groups to make plausible arguments, & to prevail.
- The result: a legal landscape that Jackson Pollack could have fashioned.

What's urgently needed: Steps toward shrinking the indeterminacy

- Our chaotic patchwork of health law decisionmakers isn't about to become more orderly.
- But enhanced knowledge about clinical outcomes could contribute to more rational decisions.
- So would an agreed-upon framework for striking balances between costs & benefits.

Toward a Pragmatic Approach to Benchmarks for Quality & Costs

- Needed: A sustainable way to evaluate clinical interventions & develop evidence-based, cost-sensitive, transparent practice protocols.

Challenges:

- America’s diverse public & private financing & delivery systems preclude a one-size-fits-all approach to development of payment protocols
- Providers resist clinical outcomes research and protocol development that challenge widely-used tests & treatments.
- Culture: Resistance to idea of denial of beneficial care

A Model: The “Council on Clinical Standards”

Strategy – Medicare First: Make Medicare an example, but build a template that’s adaptable to other public programs & the private sector:

3 Major Tasks:

- Development of a long-term agenda for clinical outcomes research.
  - Administration of peer-reviewed grant-making process for conduct of this research.
- Development of cost-benefit trade-off principles to guide the crafting of clinical payment protocols.
- Development & periodic review of evidence-based payment protocols for acute care, health-promotion, and supportive & comfort-oriented care.

Process: Institutional Design for the Management of Interest-Group Conflict

Strategy – Channel discontent into the system rather than to outside actors, i.e. Congress, with power to scuttle efforts that ruffle feathers:

- Provide ample opportunity for affected interests to state their concerns & their supporting arguments.
- Enhance political durability via strategic use of budgeting mechanisms and administrative law to insulate decision-making processes from undue Congressional & White House interference

Composition of "Council on Clinical Standards"

- Independent agency, apart from DHHS: Council doesn't report to DHHS leadership.
- Council Members: Staggered terms; appointed in bipartisan fashion from roster of preeminent figures in medicine & health policy
- Own staff.
- Insulate budgeting from annual appropriations process.

Working Agenda

- Strategic Plan for clinical outcomes research: evolve with science base & changing perceptions of need.
- Cost-benefit trade-off principles: Negotiation model; Tolerate inconsistencies across clinical contexts
- Biggest challenge: Development of payment protocols (binding on Medicare & other public programs?).

Payment Protocol Development

- Agenda of medical practice issues deemed to be high priorities for protocol development, based on scientific opportunity and clinical & budgetary importance.
- Development of protocols by time-limited study committees.
- Study committee process: Opportunities for public input; requirement of reason-giving; opportunities for appeal ("arbitrary & capricious" test)
- Adoption or rejection of protocols by Council
- Judicial Review

Potential Benefits

- Accelerate outcomes research
- Transparency in cost-benefit decision-making
- Reduction in clinical practice variation
- Basis for menu of standards of care for providers and health plans