How the Government Built a Cage Around Healthcare, One Law at a Tim

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Abstract

This essay traces the regulatory history of U.S. healthcare from 1946 to the prese covering the Hill-Burton Act, Certificate of Need laws, EMTALA, the Stark Law ACA's physician-owned hospital ban, and 340B. Key facts and figures:

- Hill-Burton (1946): $4.6B in grants and $1.5B in loans to roughly 6,800 healthc facilities across 4,000+ communities

- CON laws: First mandated federally in 1974 via the National Health Planning a Resources Development Act (NHPRDA); federal mandate repealed in 1987; roug states still have some form of CON today

- EMTALA (1986): Unfunded mandate; uncompensated care represented 55% of emergency room care in 2009 and about 6% of total hospital costs

- Stark Law (1989, expanded 1993/1995): Strict liability statute; civil penalties up $15,000 per violation, up to $100,000 per circumvention scheme; Adventist Heal paid $118.7M (2015), Halifax Hospital $85M (2014)

- ACA (2010): Closed the "whole hospital" Stark exception for new physician-ow hospitals; CBO scored the closure at $500M in deficit reduction over 10 years

- 340B (1992): Originally a small safety-net drug discount program; by 2023, cov entity 340B purchases exceeded $66B/year; disproportionate share hospitals acc for nearly $52B of that

The essay argues that each of these regulations was a rational response to a real problem but that collectively they created a locked regulatory architecture that every major investment and go-to-market decision in health tech today. Understanding the causal chain that produced these laws is table-stakes knowle for anyone deploying capital or building companies in this space.

How the Government Built a Cage Arou Healthcare, One Law at a Time

> The Post-War Hospital Boom and Its Unintended Consequences

Here is something worth sitting with for a moment. The fundamental architectu American healthcare regulation, the stuff that determines who can own what, wh refer to whom, which drugs get discounted, and whether a hospital can build a n wing without government permission, was not designed by anyone. It was not th product of a master plan. It was a series of improvised responses to the unintend consequences of the previous improvised response, each one adding another laye

complexity onto a system that was already straining under the weight of the last that sounds familiar to anyone who has spent time in enterprise software or lega financial services, the analogy is not accidental.

Start in 1946. World War II just ended, soldiers are coming home, the country is growing fast, and there is a serious shortage of hospital beds, particularly in the South and Midwest. More than 40% of the nation's counties had no hospital at al President Harry Truman wanted national health insurance, which was politically radioactive at the time. The American Medical Association was furiously lobbyi against anything that smelled like socialized medicine. The compromise that em was the Hospital Survey and Construction Act, known as Hill-Burton after its Se sponsors, Lister Hill of Alabama and Harold Burton of Ohio. It was elegant in it simplicity: the federal government would give states grants and loans to build hospitals, and in return those hospitals would serve the public regardless of abil pay, at least for a "reasonable volume" of care, a term so vague it went basically unenforced for the first 20 years.

The scale of what followed was enormous. Between 1947 and 1971, Hill-Burton dispersed more than $3.7 billion in federal funding matched by $9.1 billion from and local governments. By 2000, the program had directed over $4.6 billion in gr and another $1.5 billion in loans to roughly 6,800 facilities in over 4,000 commu Alabama, of all places, created more Hill-Burton hospital beds per capita than a state except Mississippi during the program's first decade. The South, which wa loudly opposed to big government in principle, was quietly the biggest recipient federal healthcare infrastructure dollars in practice. That tension between state ideology and actual behavior would become a recurring theme in American heal policy.

The "separate but equal" clause embedded in Hill-Burton is also worth a note. H trying to secure Southern votes, added a provision explicitly permitting racially segregated facilities, which was the only time in the 20th century that racial segregation was codified in a federal statute. A federal court struck it down in 1 and Hill-Burton became, somewhat ironically, a driver of hospital desegregation

afterward. Healthcare policy producing outcomes its architects did not intend: a pattern established very early and never really broken.

By the late 1960s, the problem was no longer too few hospital beds. The problem too many, and too many of them being filled. Researchers had identified what ca be called the Roemer Effect, named after the health economist Milton Roemer, w was basically the observation that hospital bed supply strongly predicts hospital utilization. Build the beds, fill the beds. This was not purely a supply-demand phenomenon. Fee-for-service reimbursement meant that hospitals were paid for service they rendered, and the introduction of Medicare and Medicaid in 1965 injected massive new demand into a system that was already oversupplied. Healt spending started climbing in ways that alarmed policymakers, and the question how to pump the brakes became urgent.

The Roemer Effect and the Certificate Need Era

The answer Congress arrived at in 1974 was Certificate of Need, or CON, laws. T logic was straightforward even if the execution was not. If you control the supply healthcare facilities and equipment, you can prevent the kind of duplicative, was overbuilding that was driving up costs. If a hospital wanted to add beds, build a wing, or buy a major piece of diagnostic equipment above a certain dollar thresh had to prove to a state planning agency that the community actually needed it. T National Health Planning and Resources Development Act of 1974 made this mandatory across all states, creating a nationwide network of Health Systems Agencies charged with reviewing and approving capital expenditure proposals. S that did not comply risked losing federal healthcare funding.

The theory was sound enough. The problem was the evidence never really suppo it. A 1976 study by Salkever and Bice found that no significant savings in hospit costs had been achieved through CON programs, and their data actually suggest that in the first five states to adopt the laws, costs may have increased, possibly because hospitals responded to bed restrictions by investing in more expensive

equipment and technology instead. A 1980 study by Schwartz and Joskow found duplicative services, which CON was specifically designed to eliminate, were onl responsible for a small fraction of the medical cost inflation that had occurred ir preceding decades. Congress, faced with mounting evidence that the whole framework was not working, repealed the NHPRDA in 1987.

But here is the thing. Roughly 36 states kept their CON laws anyway. State healt planning bureaucracies had been built up, incumbent hospital systems had disc that CON was an extraordinarily effective tool for blocking competitors, and the political economy of repeal was unfavorable to anyone who wanted to build som new. CON became, in practice, a regulatory moat. If you were an existing hospit system in a CON state and a competitor wanted to build a new surgical center n you could challenge their CON application, delay the process for years, and rais cost of entry dramatically. The stated goal was patient welfare. The actual functi was incumbent protection. Any venture-backed health services company that ha to scale in a CON state has encountered this firsthand.

Today the CON landscape is genuinely inconsistent. Some states have eliminate CON almost entirely. Others, particularly in the Southeast, have comprehensive programs covering dozens of services and equipment categories. Florida has CO requirements for some services but not others. Texas eliminated its CON laws fc most services in 1985. The result is that if you are building a company that touc facility capacity, your regulatory environment varies dramatically by state in way bear essentially no relationship to the actual quality of care delivered in those st

Medicare, Medicaid, and the Unleashin of Infinite Demand

It would be impossible to understand any of the regulations that follow without understanding what Medicare and Medicaid did to the healthcare cost curve. Be 1965, most Americans either paid out of pocket for healthcare, had private insur through an employer, or went without. The poor and elderly were largely uninsu When Lyndon Johnson signed Medicare and Medicaid into law in July 1965 as p

the Social Security Act amendments, the government became the dominant paye the American healthcare market essentially overnight.

The actuarial estimates at the time were, in retrospect, almost comically wrong. House Ways and Means Committee projected that Medicare would cost $12 billi 1990. The actual cost in 1990 was over $110 billion. Healthcare utilization explo because the marginal cost to patients dropped dramatically, and hospitals, paid fee-for-service basis, had strong incentives to deliver more services. The combin of federally funded demand and Roemer-style supply expansion created a feedba loop that has never fully been resolved. Every major regulatory intervention in healthcare from 1966 onward can be understood as an attempt to address consequences, direct or indirect, of those 1965 amendments.

The prospective payment system introduced in 1983, which replaced cost-based Medicare reimbursement with fixed payments by Diagnosis Related Groups, was such attempt. Instead of paying hospitals whatever they spent on a patient, Medi would pay a fixed amount based on the diagnosis. This was genuinely transforma and did slow cost growth for a period. But it also created strong incentives for hospitals to discharge patients quickly, sometimes too quickly, and to code diagn in ways that maximized reimbursement. It shifted the arms race rather than endi

Patient Dumping and the EMTALA Surprise

By the mid-1980s, a different consequence of the fee-for-service and private insu system was becoming visible in emergency departments, particularly at public hospitals in major cities. Private hospitals were routinely transferring uninsured Medicaid patients to public hospitals without treating them, sometimes without stabilizing them. The practice had a name: patient dumping. Cook County Hosp Chicago documented that 89% of patients transferred to it for financial reasons minorities, 87% lacked employment, only 6% had consented to the transfer, and arrived in unstable condition. Patients who were transferred were twice as likely die.

Congress responded in 1986 with the Emergency Medical Treatment and Active
Act, EMTALA, tucked inside the Consolidated Omnibus Budget Reconciliation
EMTALA required any hospital with an emergency department that accepted
Medicare payments, which was virtually every hospital in the country given that
Medicare and Medicaid together represented roughly 44% of all medical expend
to provide a medical screening examination and stabilizing treatment to anyone
presented, regardless of ability to pay. The law was four pages long and barely n
at the time.

What no one quite appreciated was that EMTALA was an unfunded mandate. Tl
federal government required the service without providing the funding. By 2009
uncompensated emergency care represented 55% of all emergency room care and
about 6% of total hospital costs. The law effectively made emergency departmen
safety net of last resort for the uninsured, a role they were never designed to fill
for which they are spectacularly ill-suited from an efficiency standpoint. Some 1
hospitals eventually closed their emergency departments in part because of the
financial pressure. The costs that hospitals could not absorb were passed on to
insured patients through higher prices, which drove up insurance premiums, wh
increased the number of uninsured, which increased EMTALA utilization. Anot
feedback loop.

For health tech investors, EMTALA is not usually the regulation that comes up f
board discussions. But it is the silent backdrop to enormous portions of the mar
The entire emergency care management software space, the complex billing
reconciliation problem around uncompensated care, the strategic behavior of ho
systems around emergency department capacity, and the pressure on safety net
hospitals are all downstream of a four-page law that Ronald Reagan signed with
fanfare in 1986.

The Self-Referral Problem and the Rise
Pete Stark

By the late 1980s, it had become increasingly clear that doctors who owned finar stakes in facilities to which they referred patients were referring more patients t those facilities. This is not surprising in retrospect. If a physician owns a piece c lab, they order more labs. If a physician has an ownership stake in an imaging ce they order more imaging. Studies of physician referral patterns showed this effe clearly, and it was costing the Medicare program real money. Enter Pete Stark, a Democratic congressman from California with a reputation for aggressive healt policy positions and a genuine talent for making the medical community uncomfortable.

Stark I, passed in 1989 as part of the Omnibus Budget Reconciliation Act, prohi physicians from referring Medicare patients for clinical laboratory services to ar entity in which the physician or an immediate family member had a financial int It was relatively narrow and reasonably well-received, in part because clinical la were a specific and documented problem area. Stark II came in 1993, expanding prohibition to a much broader list of "designated health services," including phy therapy, occupational therapy, radiology, radiation therapy, durable medical equipment, home health services, outpatient prescription drugs, and inpatient a outpatient hospital services itself. Medicaid patients were added to the covered population. The medical community pushed back hard, arguing that this was government intrusion into clinical practice. Stark III followed in 2007, largely clarifying and tightening the exceptions framework.

The Stark Law, as it exists today, is a strict liability statute, meaning that intent not matter. A physician who inadvertently refers a Medicare patient to an entity which a family member has a financial interest has violated the law even if they l idea the interest existed and derived no personal benefit. The penalties are serio to $15,000 per service provided in violation, up to $100,000 per circumvention scheme, and exclusion from Medicare and Medicaid participation, which is a po death sentence for a physician's practice. Settlements have been enormous. Adve Health System paid $118.7 million in 2015. Halifax Hospital Medical Center pai million in 2014. Wheeling Hospital paid $50 million in 2020.

The strict liability aspect of Stark created a compliance industry unto itself. Hos and health systems spend tens of millions of dollars annually on Stark complian programs, physician compensation analyses, and fair market value assessments, designed to ensure that physician compensation arrangements are not influence the volume or value of referrals. CMS itself acknowledged in a 2020 rulemaking "ambiguities in the Stark law have frozen many providers in place, fearful that e beneficial arrangements might violate the law." The 2020 rulemaking attempt to exceptions for value-based care arrangements was specifically motivated by the observation that Stark was making it harder, not easier, to build coordinated car models.

For investors and founders, Stark is the regulatory context for almost every deal structure that involves physicians and facilities. It is why physician-owned speci hospitals look different from general hospitals. It is why physician employment arrangements at health systems are structured the way they are. It is why the contractual scaffolding around any technology company that sits between a phys and a referral destination needs very careful legal review. The law is trying to sol real problem, which is that physicians have a genuine conflict of interest when t own the facilities to which they refer, but it does so in a way that creates enormo transaction costs for everyone.

The ACA Slams the Door on Physician-Owned Hospitals

The Stark Law had always contained what was called the "whole hospital except which allowed physicians to refer patients to a hospital in which they had an ownership interest, as long as the ownership was in the entire hospital rather tha just in a specific service line. This exception had enabled the growth of physician owned hospitals, which were typically focused on highly profitable service lines orthopedics, cardiac care, and surgery, and which competed with general commu hospitals for the most profitable patients and procedures while avoiding the mor losing ones.

The hospital lobby, led by the American Hospital Association, had fought physic owned hospitals for years on the grounds that they cherry-picked the healthiest most profitable patients, leaving community hospitals stuck with the sicker, poo and more complex cases. The evidence supported this critique. The Government Accountability Office, CMS, and the Medicare Payment Advisory Commission a found that physician-owned hospitals' patients tended to be healthier than patie with the same diagnoses at general hospitals. MedPAC and GAO found that phy owned hospitals treated significantly fewer Medicaid patients. By directing high margin cases to physician-owned facilities while relying on publicly funded emergency services for complex or uncompensated cases, physician-owned hospi were, depending on your politics, either an efficient market innovation or an ela free-rider strategy.

The Affordable Care Act in 2010 resolved this debate by simply closing the whol hospital exception for new physician-owned hospitals. Any physician-owned hos that did not have a Medicare provider number as of December 31, 2010 could nc created under the exception. Existing facilities were grandfathered but subject t strict disclosure requirements, patient safety rules, and growth restrictions. The scored the closure of this exception at $500 million in deficit reduction over 10 y The door was closed, and it has stayed closed despite repeated attempts by legisl to reopen it, including the Patient Access to Higher Quality Health Care Act of

This is the proximate answer to the question posed by this essay's title. Doctors not "banned" from owning hospitals in any sweeping categorical sense. What happened is that the one legal mechanism that had allowed them to do so at scal whole hospital Stark exception, was eliminated by the ACA. Pre-2010 physician- owned hospitals still exist and still operate. New ones cannot be created for Med participating physicians who want to refer patients there. The distinction matte especially for anyone who has heard "doctors can't own hospitals" in a pitch mee and wondered if that was technically accurate. It is mostly accurate for practical purposes, even if the legal reality is more nuanced.

The 340B Drug Discount Rabbit Hole

The 340B Drug Pricing Program is one of the more quietly consequential regula in the healthcare system and one that most people outside of hospital finance an pharma market access teams did not pay much attention to until it started gener $66 billion in annual spending. It began modestly. Congress created it in 1992 th the Veteran's Health Care Act, signed by George H.W. Bush, as a response to an unintended consequence of the 1990 Medicaid Drug Rebate Program. The Medi rebate program required drug manufacturers to give Medicaid programs their b price. That sounds fine, but the best price rule meant that manufacturers, worri about triggering lower Medicaid prices, stopped giving safety net hospitals the informal deep discounts they had previously enjoyed. Safety net hospitals sudde lost access to affordable drugs for their poorest patients.

340B fixed this by requiring drug manufacturers who participate in Medicaid to offer outpatient drugs to "covered entities," primarily safety net hospitals and federally qualified health centers, at discounted ceiling prices. The spread betwe the discounted acquisition cost and the reimbursement rate the entity receives f insurers or Medicare when it dispenses those drugs flows back to the covered en subsidizing operations and services for underserved populations. That is the sta theory. The 340B ceiling price typically represents discounts of 20% to 50% off t average manufacturer price.

The program was small for years. Then the ACA in 2010 massively expanded the of eligible covered entities to include children's hospitals, cancer treatment facil critical access hospitals, rural referral centers, and sole community hospitals. Ho participation tripled. By 2021, total program sales reached approximately $44 bi a 15% increase over 2020. By 2023, covered entity 340B purchases exceeded $66 per year, with disproportionate share hospitals alone accounting for nearly $52 billion. HRSA estimates that 340B sales constitute roughly 7.2% of the entire U.S drug market.

The program's explosive growth attracted scrutiny from all directions. Senator Charles Grassley, reviewing the data, documented hospitals profiting from the 3 program by purchasing drugs at the 340B discount and then dispensing them to Medicare and privately insured patients at full reimbursement rates, keeping th

spread. The program's integrity problems are structural: there are no requireme how 340B revenue is used, most hospitals have minimal reporting obligations, a HRSA has limited regulatory authority to enforce the program's original intent. manufacturers responded by trying to restrict 340B discounts to in-house pharm rather than contract pharmacies, triggering years of litigation that continued th 2024. The Supreme Court weighed in with a 2022 decision in American Hospital Association v. Becerra that limited HHS's ability to reduce Medicare reimburse for 340B drugs without further process.

For health tech investors, 340B is operationally relevant because it affects drug procurement strategy for any company touching hospital pharmacy or outpatien dispensing. It is financially material to the unit economics of any business that touches covered entity revenue. And it is a compliance minefield for anyone buil in contract pharmacy, specialty pharmacy, or hospital revenue cycle. The gap bet the program's stated purpose and its current function is wide enough to drive a large vehicle through.

What This All Means for Investors and Builders

All of the above is more than a history lesson, though it is that too. What it actu taken as a whole, is the operating manual for why healthcare looks the way it do today. The ownership restrictions, the referral rules, the facility licensing requirements, the drug pricing architecture, the emergency care mandates, none these emerged from first principles. They are the sedimentary layers of a system has been repeatedly patched at the point of failure without ever being redesigne from the foundation.

For investors, the key insight is that regulation in healthcare is not fundamental about preventing harm, though that is the stated rationale for all of it. It is abou managing externalities in a market where the normal price signals do not work. Patients are not rational consumers of healthcare in most circumstances. Physic have information advantages that create massive agency problems. Payers are

separated from providers by layers of intermediary structure that would horrify anyone trained in microeconomics. When you add government as a dominant pay the distortions compound. The regulations described above are attempts to cons those distortions. They succeed partially and create new distortions in the proce

The practical consequence is that every major category of health tech investmen shaped by at least one of these regulatory layers. Physician-facing software lives the Stark compliance reality. Hospital technology purchasing is filtered through constraints in many states. Drug-adjacent businesses have to navigate 340B. Any company that touches emergency care is working with the cost structure created EMTALA. Revenue cycle and billing infrastructure is shaped by all of it simultaneously. This is not a complaint. It is an observation. Markets with regul complexity are markets where information asymmetry is high, switching costs ar elevated, and the companies that build durable workflows around compliance requirements tend to generate defensible positions that are hard for new entran replicate.

The other thing worth saying is that the regulatory architecture is not static. CC laws are being challenged and repealed in more states. The Stark exceptions for based care are being expanded. 340B is heading toward a more adversarial manufacturer relationship that could materially change program economics for covered entities. EMTALA faces legal pressure in the context of post-Dobbs abo restriction conflicts. The rate of change in the underlying regulatory framework accelerating, which creates both risk and opportunity for anyone building in thi space. Understanding where the laws came from, what problems they were origi trying to solve, and what constituencies they now serve is the prerequisite for ha any informed view about where they are going.

The cage was not built all at once. It was assembled incrementally, one improvis at a time, by legislators and regulators responding to real problems with imperfe tools under political constraints. The result is a system that is genuinely difficul navigate, genuinely resistant to disruption in places, and genuinely in need of th of technological and organizational innovation that is the whole point of the hea

tech investment thesis. The map of how it got this way is worth having before yo start trying to figure out how to change it.

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David Gregory Smith 2d

great summary. i am in the field most of each month with providers and administr
think the exhaustion is evident in any meeting whether its ACCESS, RHTF, Cures A
transparency rules, etc. and investors are checking out too, interest in change ev
beneficial is very low, maybe close to non-existent with the groups I work with da

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