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How did we get here? A brief history of health care regulation in the United States

By Michael Adelberg, MPP, MA

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Even the most enthusiastic supporters of the current U.S. regulatory system shrug over its patchwork nature and the overlapping mandates of its constituent parts. The present U.S. regulatory structure, as regulatory professionals well know, creates a host of regulators—varied federal actors, states, and different quasi and non-governmental organizations. Managed care plans, for example, are financially regulated by state insurance departments, accredited by the National Committee for Quality Assurance (NCQA), and those that participate in government programs (and most do) are further regulated by the various government payors of these programs. On top of these entities sit the prosecutorial powers of state attorneys general, the Department of Health and Human Services (DHHS), Office of the Inspector General (OIG), and the Department of Justice. The various regulators serve different—but rarely entirely distinct—functions.

It is the author's contention that the patchwork of regulators and regulatory activity is the result of a profound lack of consensus over the appropriate role of regulation and government oversight in health care throughout U.S. history. The result is a confusing regulatory patchwork and its piecemeal expansion over time. As political scientist Lawrence Brown notes, expansions of the U.S. regulatory state have tended be reactive, based on upon periodic "market malfunctions." For example, legislations to create and further empower the Food and Drug Administration in 1906, 1938, and 1962, were all the result of high profile drug-market failures the previous year.[1] Equally important are macro-level societal and technological changes that have grown health care exponentially as a segment of the U.S. economy and, in many important ways, as a public entitlement. As such, the health care regulatory state has haphazardly evolved to date, and will continue to evolve based on externalities—market failures, technological advances, and societal changes—rather than because of any great or consistent political vision. As Brown further notes, the U.S. health care regulatory system was built in "bits and pieces" and never "conformed to an economic theory or master plan."[2] Nevertheless, the trend toward a greater regulatory footprint and public sector presence has been the consistent (if accidental) progression. The purpose of this article is to visit important moments in the century-long "bits and pieces" progression to building our present regulatory state, with an eye toward what this means for the foreseeable future.

The pre-regulatory era, 1800s–early 1900s

It is easy to forget how small a role professional health care played in American society just a little over a century ago. At this time, Americans rarely saw a doctor, and most lived out their adult lives without ever stepping into a hospital. Local doctors provided most care in the home, and huckster healers and medicine men toured the nation selling all variety of "snake oil" miracle cures with little risk of reprisal. By today's standards, health care was not very effective, regardless of the patient's ability to pay. The improvements brought about by the public health revolution (e.g. sanitation, hand-washing, vaccinations, quarantines, and improved diet) would make the United States the world's healthiest nation—but not because of the quality of its health care.[3]

In these bad old days for health care, doctor-patient services were negotiated privately, and rarely cost much. Hospitals (which generally provided only surgery and palliative care) were almost entirely financed by religious organizations and private philanthropy, and the wealthy avoided them. There was no health insurance provided by the government or employers because there was little need. By the late 1800s, the American Medical Association and American College of Surgeons were leading efforts to develop standards for doctors and hospitals, but these were unevenly deployed across the states. State medical boards were only gradually professionalizing the licensure requirements for doctors and hospitals; while the professionalizing of other health care providers, such as pharmacists, nurses, and dentists, lagged behind.[4]

To the degree there was any health care regulation in the modern sense of the term, it was at the state level and related to drugs. By the late 1800s, most states had passed laws against the "adulteration" of drugs. But

enforcement actions were rare. For example, New York, the nation's largest and often most activist state, punished only eight people in the first decade after passing its anti-adulteration law. Other states had more enforcement actions, but penalties were often capped at the misdemeanor level, frequently $10 (perhaps $200 when inflation-adjusted to today). In general, state officials tended to only warn and persuade violators. Going after malfeasant health care providers in court was still a decidedly individual affair; private attorneys represented aggrieved individuals using Common Law precedents to charge health care providers for gross negligence or intentional deception. Historian Nancy Tomes notes that medical malpractice suits in the U.S. date back to at least the 1840s, but these, too, were rare occurrences.[5] Practically speaking, there was no federal role in terms of regulating the provision health care—promoting health quality or access to care was simply not within its purview.

Phase I: Early federal government regulation, 1900s–1960s

In 1904, Upton Sinclair's *The Jungle*, a shocking expose on the unsanitary and abusive practices in the meat-packing industry, captured the American imagination and inspired a generation of "Muckraker" journalists and social reformers (known as "Progressives") to improve the worst aspects of the newly industrialized United States. Reformers sought to professionalize health care in a variety of salutary ways, but did not have the authority to reign in the worst members of their fraternity. These reformers allied with sympathetic state governments because of government's ability to punish bad actors. Influenced by the philosophy of Positivism (the belief that unfettered human ingenuity will forever advance the state of the art in a given field), the Progressives saw little need to use the government's influence to spur health care innovations (as the National Institutes of Health, for example, does today) or incent excellence. Rather, the Progressives focused on reigning in the quacks and crooks at the "bottom" of the health care professions. As legal scholar Nancy Frank observed, "In response to health and safety problems, governmental action has always depended almost exclusively on negative sanctions."[6]

In this context, alliances were struck between leading health care practitioners and government officials to regulate the administration of (and eventually financing of) health care in the public-private model that still exists today. In this resulting model, provider associations seek to advance the bell curve of providers in their profession through learning forums, accreditations, model curriculum for colleges, codes of conducts, etc. State government supplies the "muscle" via state-level boards (comprised largely of leading members of the profession) that govern the licensure process and oversight of each profession. Additionally, under the guidance of the state board, the state applies limited oversight resources to investigating allegations of bad conduct and punishing the worst providers. The quantity of resulting sanctions is limited. For example, even today, state medical boards collectively only sanction 2,000-3,000 doctors a year (under .5% of practicing physicians). Nevertheless, a reasonable argument can be made that the "self-improvement" efforts of the provider associations and other self-policing mechanisms mitigate the need for the heavy hand of government for the large majority of providers.[7]

For institutional health care providers (e.g., laboratories, hospitals, nursing facilities, managed care organizations), the public-private regulatory model evolved in a similar, but not identical, manner. Regulators, often prompted by scandalous episodes and public outcry, needed to evolve a more powerful regulatory tool than licensure for institutional providers. With the passage of the Pure Food and Drug Act in 1906, inspection of vaccine-producing laboratories became the national standard, and the door opened to the regulation of health care via on-site inspection.

The Significance of the Pure Food and Drug and Its Successors: The Pure Food and Drug Act of 1906 established the Food and Drug Administration (FDA), arguably the first modern federal regulatory agency, and federalized the oversight of drug production and distribution. It also expanded the federal government's regulatory authority beyond strict quality assurance (i.e., unadulterated drugs) by opening the door for the federal government to regulate certain health communications (e.g., labeling requirements, adherence to U.S. Pharmacopoeia nomenclature). By 1940, the act was expanded to forbid the dispensing of drugs without a physician prescription, empower the FDA to issue rules to further define legislation, set requirements for pharmacist and doctor records, and require pre-market testing before a drug can enter the market. The expansion of the FDA's purview set important precedents from which later policy makers would draw important lessons regarding the scope of regulatory activities, and the appropriate role of the federal government in the process.[8]

Not long after the passage of the Pure Food and Drug Act, the American College of Surgeons (the forerunner of Joint Commission on Accreditation of Health Care Organizations [JCAHO]), spurred by Muckraker revelations of diseases being spread in unsanitary hospitals, implemented a national system for assuring that hospitals were complying with the leading sanitary and health care practices of the day. In 1918, the

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year of the first national hospital inspection, only 89 of 692 inspected hospitals "passed" the inspection. Today, JCAHO conducts about 17,000 inspections a year, nearly all of which result in at least some findings that require corrective actions.[9] Importantly, the self-inspection model implemented by the hospital community has saved it from the more punishment-oriented government-run inspection programs under which labs and nursing homes labor.

Rulemaking and Civil Monetary Penalties as Regulatory Innovations: Starting in the 1930s during the activism of the New Deal, regulatory agencies displayed increasing discretion in clarifying legislation and issuing rules that were tantamount to law (rulemaking authority for federal agencies was formalized in the Administrative Procedures Act of 1946). Concurrently, federal agencies were gradually given discretion to impose non-criminal penalties (violations rather than crimes). In the case of the FDA, this led to a dramatic reduction in FDA-initiated criminal prosecutions between the 1930s and 1950s, even as the FDA dramatically stepped up its regulatory activities. These twin expansions of regulator discretion also had the unintended consequence of allowing the scope and complexity of regulatory activities to grow exponentially. The modern-day nursing home inspection for example, with its 200+ points of compliance, and 12-box grid for scoring non-compliant findings, would have been inconceivable without these regulatory innovations. Similarly, the advent of civil monetary penalities as the principal sanction for serious violations keeps regulatory violations out of the courts, greatly saving litigation time and expense for both regulator and regulated.[10]

Importantly, while the expansion of the health care regulation and the government's role as regulator was considerable through the first half of the twentieth century, the scope of the regulatory activity was generally very limited. Government actions in health care were largely confined to the traditional regulatory sphere, detecting individual failures and punishing them. However, the prosperity and increased expectations following World War II laid the groundwork for increased public budgets and purviews, and this inevitably would remake and dramatically expand the government's role in health care.

Phase II: Federal government as financier and health care improver, 1960s–present

Higher health care costs, longer lives, and the idealism of the 1960s led to the creation of the Medicare and Medicaid programs to finance health care for the nation's elderly, disabled, and low-income recipients. The creation of these programs, coupled mandates stemming from landmark civil rights law and court decisions, established the federal government as the main guarantor in the United States for health care access to all (or most) Americans, and effectively established health care as a public entitlement. With the creation of Medicare and Medicaid in 1965, the federal government became the largest health care payor in the United States in the historical blink of an eye.

Because of the size of the populations they serve, the large majority of health care providers elected (and still elect) to participate in the Medicare and Medicaid programs. Though it was not envisioned in 1965 when the programs were created, it is probably fair to state that today the majority of health care providers are as dependent on Medicare and Medicaid funding as the programs' beneficiaries. Participating in these programs comes with strings—conditions of participation, reporting requirements, and various federal standards that aim at promoting health care access and quality. In just one example, home health agencies (HHAs) that participate in Medicare and Medicaid (and given the dependence of the populations they serve, virtually all HHAs must participate) must maintain longitudinal records on the health status of people they serve through a federally-mandated reporting tool, the Outcomes and Assessment Information Set (OASIS). HHAs are subject to audits and periodic inspections that frequently result in significant penalties. For HHAs and other providers, participation in Medicare and Medicaid has largely "federalized" health care regulation, even though states are frequently the entity charged with conducting the inspections to enforce federal standards.[11]

While no one can doubt the enormous impact that Medicare and Medicaid have had on health care access, it is fair to note that remaking health care practices and the health care market were not the reasons for the creation of those programs. Nonetheless, the expansion of "defined benefit" health care programs to the nation's elderly, disabled, and low-income recipients has profoundly reshaped the health care provider landscape and economy.

The Federal Government as Health Care Change Agent: In the 1970s, deliberate federal intervention designed to influence the practice of health care became common practice. Under the 1973 HMO Act, for example, the federal government issued over $300 million in direct federal support to start-up managed care organizations and required many employers to offer managed care as an option to their workers (resulting in the growth of the industry from 30 to 250 managed care organizations in nine years). In another example, Medicare reimbursement was (and is) tampered with annually to incentivize medical schools and hospitals to

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train more or fewer specialist or primary care physicians. The growth of federal health agencies in the late 1960s and 1970s (e.g., Centers for Disease Control, National Institutes of Health, and the Agency for Health Research and Quality) established the U.S. federal government as the single largest change agent in the world for advancing the science and effectiveness of health care. Importantly, these new roles take the federal government well beyond the traditional regulatory role of identifying and correcting individual transgressions.[12]

By the 1980s, an extensive federally-dominated health care regulatory framework had evolved in a model that splits regulatory authority across numerous actors, relies on centralized rules, and dramatically expands the purview of government (particularly the federal government) across all aspects of health care. But despite (or to some degree, because of) the multiplicity of government regulatory actors, critics decry the failures of existing regulatory strategies—particularly the inability to address systemic failures (e.g., the continued persistence of preventable deaths due to medical errors in hospitals; failures of different cost-containment activities in government health programs). Meanwhile, health care providers ("among the most heavily regulated" of any professionals in the U.S., according to health economist Robert Field) seek to cope with sets of rules, reporting requirements, and due diligence demonstrations that have only an indirect bearing on the treatment of individual patients. This, in turn, has given rise to process-focused health care compliance officers and their staffs who perform the critical coordination between the health care provider and the various regulatory processes that govern health care.[13]

What might come next: The 2000s and beyond

The din of complaints against the existing health care regulatory model lays the ground for continued evolution. As noted previously, the current regulatory landscape is the result of a series of incremental changes, not far-sighted policy. This is not necessarily bad, because ad hoc systems, by their nature, are innovation-ready. Indeed, innovations are emerging in health care regulation:

- **Performance measurement:** Though not yet prevalent, more health care regulators are moving toward regulatory programs that measure performance, rather than statutory compliance. Performance measurement collects data from multiple channels and relies on balanced scorecards that provide overall assessments of provider performance that are based on the end-result for patients. In contrast, strict compliance programs rely on discrete pass/fail process measures that make no distinction between excellence and adequacy. In what might signal an evolution away from process measures, new Medicare drug plans are examined through more than a half dozen mechanisms (from claims audits to customer satisfaction surveys) and Medicare regulators consider overall performance before imposing sanctions, while scaling back the number of per capita on-site inspections.[14]
- **Public reporting:** Advances in information technology and consensus around "evidenced based" practices make it possible for regulators to collect provider-level data and make that data available for public use in comparison shopping. Already, nursing homes, home health agencies, and hospitals have quality-data information posted on the Internet for public use. States such as Pennsylvania post provider-level data on hospital errors on the Internet also.[15] Over time, these comparison tools will grow in their functionalities, ease of use, and level of use by the public. In this way, regulators will subtly influence purchasing behaviors as an adjunct to traditional regulation.
- **Pay for performance:** Public payors are looking to give incentives to providers for doing a better job in delivering health care. Medicare has cautiously introduced "incentive" payments into Medicare hospital reimbursement, and Congress is inching closer to legislation that will link annual Medicare payment increases for physicians to quality outcomes reporting—a necessary first step for eventually instituting a national physician-oriented pay-for-performance program.[16]
- **Marketplace surveillance:** Traditional compliance approaches are gradually being augmented by market/customer-facing surveillance activities. Several state attorneys general now utilize aggregated customer complaints to direct limited investigatory resources; the DHHS Inspector General and Government Accountability Office have used (and will continue to use) mystery shopping activities to assess provider call centers; the FDA becomes more reliant on ever-improving post-market surveillance to monitor drug safety; and DHHS now uses customer satisfaction surveys as a tool for assessing the quality of Medicare health plans. As health care providers and regulators both strive to become more consumer oriented, and the sophistication of these emerging market-surveillance tactics grow, this trend will continue.[17]

Collectively, these emerging regulatory practices point toward a future in which the traditional regulatory posture (i.e., rules-oriented, focused on failures, rigidly consistent in the conduct of activities) is gradually replaced by a multifaceted regulatory posture that is more concerned with wholistic performance, the customer's experience, and subtle ways to positively influence provider behavior. That this trend has already

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begun is beyond doubt; whether it will eventually proceed so far as to create a third distinct stage in the history of U.S. health care regulation is an intriguing question.

Historical periods do not begin and end neatly, and certainly the time periods and sampling of historic bell-weathers offered in this article are not beyond challenge. Ultimately, precise dates and specific incidents are trivia. What matters are the broad trends, and it is worth noting that the gradual shift from the historical default regulatory tactics (e.g., inspections and licensure) toward ascendant practices (e.g., performance measurement and public reporting) is occurring without a single identifiable champion or discernible partisan fault lines—which suggests an evolution that borders on inevitable. In coping with the changes, health care compliance professionals may need new skills (e.g., statistical sampling, data extraction and trending, qualitative research methods) and new tactics (e.g., mystery shopping, complaints validation and aggregation, performance dashboards) to keep up with a health care regulatory model that will not stop changing. ■

1. See Lawrence Brown, "The More Things Stay the Same, the More Things Change," in *History and Health Policy in the United States* (Rutgers University Press: New Brunswick, NJ, 2006), pp 42, hereafter cited as "Brown." Also see Robert Field's *Health Care Regulation in America* (Oxford University Press: New York, 2006), pp 116-122, hereafter cited as "Field" for a discussion of the circumstances and legislation that led to the expansion of the FDA's authority.
2. See Field's prologue and Brown pp 36.
3. Perhaps the most respected overview of the great advances in U.S. public health is John Duffy's *The Sanitarins: A History of American Public Health* (University of Illinois Press: Urbana, IL, 1992).
4. This history of the American Medical Association and American College of Surgeons, the predecessor to the Joint Commission on Hospital Accreditation is discussed in Field. See pages 21-6 for a discussion of the early history of the AMA; see pages 41-4 for a discussion of the American College of Surgeons and the founding of JCAHO.
5. See Nancy Frank's Ph.D. Dissertation, *From Criminal Law to Regulation: A Historical Analysis to Health and Safety Law* (Garland: New York, 1986) pp 83-4, 106-7. Hereafter cited as "Frank." Nancy Tome's historical discussion of early medical malpractice is contained in *History and Health Policy in the United States*, p 90.
6. There are numerous historical works on the Progressives, particularly recommended is John Allen Gable's *The Bull Moose Years: Teddy Roosevelt and the Progressives* (Associated Faculty Press, 1978). Nancy Frank's statement is in Frank, p 23.
7. See Field, chapters 2-5. State Medical Board sanctions are specifically discussed on page 22.
8. See Field, 117-122, for a succinct history of the expansion of the FDA's regulatory authority. Frank notes that despite its broad mandate to inspect the nation's vaccine labs, it took the FDA many years to develop the apparatus to actually fulfill the mandate; see Frank, 93-108, for a discussion of the early history of the FDA as a regulator. Finally, see www.FDA.gov, Legislative History, for a chronology of the expansion of the agency's growth and enabling legislation.
9. Field, 43-6.
10. See Frank, 175-91 for detailed discussion of the development and legal arguments behind the establishment of "violations" as the appropriate sanction for non-criminal transgressions detected by regulators. See Frank 112-3 for a table charting FDA-initiated prosecutions.
11. For good overviews of the creation of Medicare and Medicaid, see Field. Also see the provocative chapter "Misunderstanding Health Care" in Theodore Marmor's *America's Misunderstood Welfare State* (New York: Basic Books, 1990) for its defense of the public financing of health care. For information on regulation of HHAs and the Ouctomes and Assessment reporting tool, see www.cms.hhs.gov/OASIS.
12. A good discussion of the HMO Act of 1973 is provided by Bradford Gray in "The Rise and Decline of the HMO" in *History and Health Policy in the United States*. Also, see Field, 58-60 and 98-104, for a discussion of how Medicare payment is used to influence health care professionals and practices.
13. Field, 3.
14. The Federal Government's Medicare Part D compliance approach has been explained in numerous public forums. One such explanation that is easily available to HCCA members is "Part D Oversight Strategy," by Laura Minassian-Kiefel in *Medicare Prescription Drug, Part D*, in the Compliance Conference materials, September 2006.
15. Government listing of nursing home, home health, and hospital performance data is found on the Centers for Medicare and Medicaid Services Web site (www.medicare.gov), see Nursing Home Compare, Home and Health Compare, and see www.hospitalcompare.hhs.gov for publicly reported hospital quality information. Commonwealth of Pennsylvania hospital errors reporting program is summarized in "Department Of Health Releases Guidelines To Hospitals For Reporting Medical Errors, Other Serious Incidents," Press Release, Pennsylvania Department of Health, May 1, 2006. Other states have instituted hospital public reporting programs as well.
16. CMS's pay-for-performance programs include the Hospital Quality Initiative and programs that provide bonus payments for hospitals that consistently practice certain pre-identified best-practices. This is best summarized in the federal fact sheet, "Hospital Quality Initiatives" on the CMS Web site (www.cms.hhs.gov.)
17. For an overview of the move toward marketplace surveillance in health care regulation, see the author's "The Quiet Revolution in Health Care and Health Product Regulation," *RPM Report*, December 2006, pp 43-5.

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