Regulation of health care in the United States: complexity, confrontation and compromise

Regulação dos cuidados de saúde nos Estados Unidos: complexidade, confrontação e compromisso

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Resumo

Os Estados Unidos têm o maior sistema de saúde do mundo, e a regulação que o supervisiona é imenso e complicado. A estrutura federal do Governo americano que divide os poderes entre o Governo federal e os Estados, potencia essa complexidade. Maior complexidade é acrescentada pela supervisão privada, incluindo a autorregulação de importantes aspetos do sistema. Esta teia de autoridades regulatórias cria um terreno fértil para a competição e confrontação entre várias entidades regulatórias, tal como está refletido na reestruturação regulatória para sectores chave. Os médicos são regulados por leis estatais de licenciamento, mas a profissão detém uma influência considerável sobre esse processo, tal como sobre outros aspetos da formação e prática médica. A regulação hospitalar é dominada por uma organização privada controlada pela indústria. Os seguros de saúde são primordialmente regulados pelos Estados. Medicamentos e dispositivos médicos são primordialmente regulados pelo Governo federal. Apesar deste sub-contexto de complexidade e competição, o sistema de saúde pode ser visto como uma simbiose na qual os sectores privado e público se juntam numa colaboração implícita que tem permitido que o sistema de saúde americano tenha crescido e florescido.

Palavras Chave:
Estados Unidos, regulação em saúde, complexidade, Governo federal.

Abstract

The United States has the largest health care system in the world, and the regulatory apparatus that oversees it is commensurately large and complicated. Considerable complexity is engendered by the federalist structure of American government, which divides powers between the federal government and the states. Additional complexity is added by private oversight, including self-regulation of important aspects of the system. This web of regulatory authority creates the opportunity for competition and confrontation between different kinds of regulators, as reflected in the regulatory structure governing four key sectors. Physicians are regulated through state licensing laws, but the profession retains considerable influence over that process as well as other aspects of education and practice. Hospital regulation is dominated by a private organization controlled by the industry. Health insurance is primarily regulated by the states. Drugs and devices are primarily regulated by the federal government. Despite this subtext of complexity and competition, the system can be seen as one of symbiosis in which the public and private sectors join in an implicit collaboration that has enabled the American health care system to grow and thrive.

Key Words:
United States, health regulation, complexity, federal government.

Introduction

The United States has the largest health care system in the world, accounting for more than $3.2 trillion in spending in 2015.[1] This translated to more than $9,990 per person and almost 18 percent of the overall economy.[1] Each of those figures is close to double the average for all developed countries.[2] This size makes the task of regulating the system especially challenging.

Three underlying attributes characterize the regulation that oversees the system. It is extraordinarily complex, with multiple layers of authority operating under both public and private auspices. The different loci of power provide ample opportunity for confrontation and conflict between them. However, compromise and collaboration between the industry and its regulators have enabled the system to grow and thrive.

Complexity in American health care regulation

The most significant source of regulatory complexity is the federalist structure of American government. The United States Constitution divides the power to enact and enforce laws between the federal government and the states, although their jurisdiction can sometimes overlap.[3] In the event of conflict, federal law takes precedence, however regulation at both levels can cover different aspects of the same activity.

The power of the states is "plenary", meaning they can regulate any activity related to the general welfare, unless authority is explicitly given to the federal government or reserved to the people. This includes jurisdiction over health care. As a result, there are 51 different systems of laws governing basic health care regulation, one for each state and one for the District of Columbia. Most of these systems delegate some authority to municipal and county governments, most notably authority over some aspects of public health.

The federal government's powers are "enumerated", meaning they are limited to those that the Constitution specifically describes. With regard to health care, two such powers are especially important, the power to regulate commerce between different states and the power to impose taxes and spend the resulting revenue to promote the general welfare. Most federal health care programs are implemented by component agencies of the Department of Health and Human Services (DHHS), a cabinet-level agency that reports directly to the president.

An additional layer of complexity is created by the role of private regulators. They are particularly important in overseeing physician practice and hospital operations. Some represent outside interests, such as insurance companies, and some represent the industry, itself (table 1).

Table 1 - Key bodies with regulatory authority over health care in the United States

Federal	State	Local	Private
Department of Health and Human Services • Centers for Medicare & Medicaid Services (CMS) • Food and Drug Administration (FDA) • Centers for Disease Control and Prevention (CDC) • Health Resources and Services Administration (HRSA) • National Institutes of Health (NIH) • Agency for Healthcare Research and Quality (AHRQ)	Boards of Medicine	Municipal and county health departments	Organizations controlled by the industry/profession • Liaison Committee on Medical Education • Medical specialty boards • Joint Commission • National Committee on Quality Assurance
Veterans Health System (part of Department of Veterans Affairs)	Departments of Health		Insurance companies • Reimbursement rules
U. S. Department of Agriculture	Departments of Insurance		Hospitals • Requirements for membership on medical staffs and for performing procedures
Environmental Protection Agency (EPA) (independent agency)	Departments of Welfare		
Occupational Safety and Health Administration (OSHA) (part of Department of Labor)	Departments of Aging		
Federal Trade Commission (FTC)			

Confrontation in American health care regulation: history and structure

America's complex regulatory landscape emerged from a history of competing forces that vied for influence. The resulting patchwork of oversight is illustrated by the regulation of four key sectors: physicians, hospitals, insurance companies, and medical products.

Regulation of physicians

The origins of physician regulation lay in efforts of the profession to promote its own standardization. Today it is regulated by elements at the federal, state and private levels (table 2). The push for regulation began in 1847 with the founding of the American Medical Association (AMA), which had the goal of improving the quality and reputation of what was seen as a somewhat disreputable profession.[4] The Association's first initiative was to promulgate a code of ethics. This was followed a campaign to promote the enactment of licensure laws and to standardize physician training. These efforts took several decades, but by the beginning of the twentieth century, the AMA had achieved the quality improvement it sought through a regulatory system over which it maintained substantial control.

Between 1873 and 1915 every state enacted legislation requiring physicians to obtain a license before practicing.[5] These laws were fairly consistent in giving authority to a medical board composed of senior members of the profession to set and enforce standards. The enactment of these laws was a significant political achievement for the AMA.[5(p 121),6] Government-mandated licensure added credibility to the profession's oversight and the force of law to enforce it, however a state-based system created a patchwork of laws and the need to lobby for their enactment separately in each state. A single centralized authority at the federal level would have been simpler, but the profession feared it would have limited ability to influence a large federal bureaucracy. By pursing separate initiatives in each state, the ACA forestalled federal intervention while creating a comprehensive regulatory system over which it could hold continuing sway.

With the licensure initiative on the path to success, the AMA next promoted the standardization of medical training. By the early twentieth century, the United States had hundreds of medical schools, many of extremely poor quality. To encourage standardization, the Association created a Council on Medical Education in 1904 to recommend a required course of study, and it engaged the Carnegie Foundation for the Advancement of Teaching to assess every school for compliance. The Foundation hired a young educator named Abraham Flexner to visit and evaluate the schools. His report, published in 1910, found substandard education in half of them and recommended their closure, which occurred over the next several years. The result was that the United States had fewer schools, but those that remained offered more rigorous training and imposed higher standards for admission.[5(pp116-123),7]

Just as it had retained influence over the licensure process, the AMA maintained control over the system of medical education through several nonprofit organizations that oversee various aspects of it. Among these are the Liaison Committee on Medical Education, which accredits medical schools, the Accreditation Council for Graduate Medical Education, which accredits postgraduate residency training programs in hospitals, and the Educational Commission for Foreign Medical Graduates, which sets standards for graduates of foreign medical schools.[6(pp25-26)]

Three other nonprofit organizations created by the AMA extended its influence over additional aspects of physician practice. The National Board of Medical Examiners administers the examinations required for licensure in all states. The Federation of State Medical Boards coordinates the licensure activities of the states. The American Board of Medical Specialties coordinates the activities of 24 boards that certify competence to practice in specific specialties.[6(pp25-28)]

In recent decades, the AMA's central regulatory role has been increasingly challenged by the federal government through a range of agencies and programs. The most important is the Medicare program, which provides health care coverage for the elderly and totally disabled. Its reimbursement represents a substantial portion of the revenue of many physician practices, giving it tremendous influence over the profession. Medicare's regulatory reach begins with funding for the training of residents and fellows in hospitals after they graduate from medical school. This support determines the number of new physicians who receive training and therefore the size of the physician workforce.[8] Medicare also shapes the desirability of each specialty as a field of practice by determining its earning potential. It does this through a fee schedule known as the Resource-Based Relative Value Scale (RBRVS) that sets payments according to the relative amount of effort and practice expense required to perform each kind of procedure.[9] Many private insurance companies use RBRVS in making their own reimbursement decisions.

Among other regulatory initiatives, Medicare implements incentives to promote the "meaningful use" of electronic medical records.[10] Along with its companion program Medicaid, which provides coverage for the poor, it imposes complex rules for submitting reimbursement claims and limitations on receiving or paying remuneration in return for the referral of patients.[11] Compliance requires physicians to invest significant resources in the business side of their practices and guides the structure of professional relationships.

Medicare has also initiated experiments with new forms of reimbursement as alternatives to the traditional fee-for-service model under provisions of the Affordable Care Act (ACA), also known as Obamacare.[12] One such experiment involves the use of bundled payments that combine reimbursement for all providers who take part in treating a patient's condition. Another offers incentives for physicians and hospitals to coordinate their activities through Accountable Care Organizations (ACOs), entities that can receive reimbursement bonuses if they meet targets for efficiency and quality in treating patients with complex conditions.

Other federal agencies that play important regulatory roles include the Health Resources and Services Administration (HRSA), which administers physician workforce programs that encourage primary care practice and provides loans for medical students.[13] The agency managed programs in the 1960s to expand the country's overall physician complement. HRSA also administers the National Practitioner Data Bank (NPDB), a repository of information on disciplinary actions and lawsuits against physicians, which has made it more difficult for physicians who have been disciplined in one state to continue practicing by moving to another.[13] The Office for Civil Rights of DHHS enforces the Health Insurance Portability and Accountability Act (HIPAA), which requires physicians, along with all health care providers, to safeguard the confidentiality of patient medical information.[14,15[

The final piece of the regulatory landscape for physicians is oversight by two kinds of private organizations other than those controlled by the profession. Hospitals impose requirements on physicians for admitting patients and rendering clinical services based on indicia of quality. After a physician joins the staff of a hospital, he or she is subject to continuing oversight, including review of adverse patient outcomes. Today, many hospitals add economic criteria to their physician oversight, including measures of efficiency and consistency with the institution's overall workforce needs.[16,17]

With the advent of managed care in the 1970s, insurance companies began to take an active role in overseeing the care they finance. They now require physicians to meet criteria for quality, efficiency and cost in order to be included in their networks and eligible for reimbursement. They may also require physicians to follow specified protocols in treating complex conditions.[18]

Regulation of hospitals

The first American hospital, Pennsylvania Hospital, was founded in 1751 with a primary mission of housing the sick poor, who did not have the resources to recuperate at home. Other hospitals with similar missions opened over the course of the next century, many founded by re-

Table 2 - Key regulatory elements for physicians

Federal	State	Private
Centers for Medicare & Medicaid Services • Medicare payments for post-graduate training • Medicare participation rules • Medicare reimbursement rates (RBRVS) • Medicare incentives for "meaningful use" of electronic medical records • Medicare reimbursement experiments	Medical Boards • Licensure for practice • Oversight of practice and discipline	Medical profession (through the AMA) • Accreditation of medical schools • Administration of national licensure examination • Specialty board certification
Health Resources and Services Administration • National Practitioner Data Bank • Health care workforce management • Medical student loans		Insurance companies • Managed care network selection • Managed care practice oversight
		Hospitals • Medical staff membership and clinical privileges

ligious organizations. Their transformation into centers of sophisticated care began in the late nineteenth century with the development of new technologies, such as anesthesia and antisepsis for performing surgery.[5(p130)]
States require that hospitals obtain licenses to operate, but for the past 60 years the most comprehensive oversight has come from a private organization controlled by the industry (table 3). The Joint Commission, formerly known as the Joint Commission on Accreditation of Hospitals, was created in 1952 through the merger of three smaller organizations to accredit hospitals based on regular audits of various quality measures. In most states, accreditation by the Joint Commission is not legally mandated, but it is required for reimbursement by Medicare, Medicaid, and most private insurance plans, so it is necessary for financially viability. Lack of accreditation would also severely damage a hospital's reputation.[19] The Joint Commission is organized as a nonprofit corporation that is controlled by the institutions subject to its oversight, a group that includes almost every hospital in the United States. Critics see a conflict-of-interest in this self-regulation and the possibility of lax enforcement. The industry sees the Joint Commission as an aggressive regulator that is more rigorous than most state governments would be.
While most states have ceded a primary role in regulating hospital quality to the Joint Commission, several of them oversee other aspects of hospital operations. Certificate-of-need laws in 34 states require hospitals to receive government permission before opening a new facility, service or beds.[20] Several states mandate that hospitals publicly report costs and outcomes for some complex procedures, such as open-heart surgery.[21] Some also require hospitals to report medical errors to Patient Safety Authorities that can investigate underlying causes.[22]
As with the regulation of physicians, the federal government also plays an important role. The first federal foray into hospital regulation came in 1946 with the Hill-Burton Act, which allocated billions of dollars for the construction of new hospitals and the expansion of existing ones, mostly in rural areas.[5(p350),23] Hospitals that accepted funding were required to abide by regulations that required minimum amounts of indigent care and prohibited discrimination based on race.
Today, most federal regulation is imposed through the Medicare program, as it is for physicians. Most acute care hospitals rely on Medicare for much of their revenue, so they have little choice but to accept the program's rules of participation and are especially responsive to incentives created by the structure of Medicare reimbursement.[24] During the early years of the program, hospitals were paid based on their actual cost of providing care with no reward for efficiency, and costs rose rapidly as a result. In 1983, the reimbursement method changed to one that paid a set amount based on each patient's diagnosis regardless of the services actually rendered according to a classification system known as diagnosis-related groups (DRGs).[25]
DRG-based reimbursement profoundly changed the nature of hospital operations and continues to influence them today. Its incentive for efficiency led to dramatic reductions in lengths-of-stay.[26] It also encouraged them to move large amounts of care to outpatient settings, which continued to be reimbursed on a fee-for-service basis. During the 1980s and 1990s, hospitals opened many outpatient clinics for ambulatory surgery, radiology, minor procedures and other services.[27]
Over the years since its enactment, Medicare's regulatory reach has extended other aspects of hospital operations. Under a law known as the Emergency Treatment and Active Labor Act (EMTALA), the program requires participating hospitals to assess and stabilize all patients who present themselves in the emergency room regardless of ability to pay.[28,29] Under the Clinical Laboratory Improvement Act (CLIA), clinical laboratories both in hospitals and physicians' offices must meet basic quality standards.[30]
The ACA empowered Medicare to promote better coordination and efficiency of hospital care through experiments with new forms of payment, such as bundled payments and ACOs, as it did for physicians. It also calls for Medicare to penalize hospitals for certain quality lapses, such as excessive numbers of readmissions of patients soon after they are discharged. Hospitals must also publicly report quality data to the Medicare program for posting on a website that patients can use in choosing among facilities.[31]
Since almost two-thirds of American hospitals operate on a nonprofit basis, the federal government also regulates them through calls for obtaining and maintaining tax-exempt status. To qualify, hospitals must demonstrate a charitable mission that includes minimum amounts of charity care, responsiveness to the needs of their communities, and limits on self-dealing with executives and board members. Adherence is enforced by the Internal Revenue Service, which can revoke an organization's tax-exemption and levy fines for noncompliance.[32]
Hospitals are also subject to federal laws that prohibit various forms of discrimination. The Americans with Disabilities Act (ADA) prohibits discrimination in public access and employment based on disability.[33] The Civil Rights Act of 1964 prohibits discrimination based on race.[34] Hospitals must also comply with the rules regarding confidentiality of patient information imposed by HIPAA.[35]
Finally, hospitals are also subject to regulation by private insurance companies, similar to that imposed on physi-

cians. Since the advent of managed care, insurers have been increasingly aggressive in reviewing expensive care before they agree to pay for it, including hospital admissions and complex procedures. Many insurers restrict the number of hospitals in their networks and negotiate substantially discounted prices for those they include. In a similar manner to Medicare, some are also actively partnering with hospitals to experiment with new payment arrangements to promote greater efficiency.[36]

Regulation of health care finance

Funding for American health care is divided fairly evenly between public and private sources (table 4). The primary public sources are Medicare and Medicaid. Medicare, which is administered by the federal government, covers more than 55 million people who are age 65 and above, totally disabled, or have end-stage renal disease.[37] The federal government also provides health care directly through public hospitals and clinics to military veterans, active duty military personnel and their families, and Native Americans who live on reservations.

Medicaid covers more than 74 million people who are extremely poor and is administered separately by each state.[38] The federal government sets standards for eligibility and coverage and pays between 50 and 80 percent of each state's cost depending on the state's average income. Prior to the ACA, Medicaid benefits were limited to certain categories of poor people, including pregnant women, children, the totally disabled, and the elderly disabled with different income thresholds for each category in each state. Under the ACA, states can choose to expand their programs to cover all residents with incomes up to 133 percent of the federal poverty level without regard to category with the federal government paying at least 90 percent of the added cost.[39]So far, 32 states have chosen to do so. States may also receive a federal contribution to cover children in families with incomes slightly above the Medicaid threshold under the Children's Health Insurance Program.[40]

The largest source of coverage for Americans is private insurance provided by employers, which covers about half the population.[41] This is an especially attractive benefit because the money paid to insurance companies by employers on behalf of workers is exempt from income tax. Those who do not have access to employer-provided insurance can purchase coverage directly from an insurance company under rules established by the ACA, and about seven percent of Americans do so.[41]

Although the federal government has the constitutional authority to regulate health insurance as a form of commerce between states, Congress has ceded primary responsibility to the states.[42] Each state oversees basic aspects of the insurance business, including the financial solvency of companies, policy terms, and premium levels. However, the federal government has intervened regarding several aspects. Among the most important federal interventions is the creation in 1973 of incentives for the development of health maintenance organizations through the Health Maintenance Organization Act, which led over the next 20 years to the growth of managed care as the predominant form of private coverage.[43] In 1974, federal legislation gave special regulatory protections to self-insurance plans that enable employers to cover their workers directly without the involvement of an in-

Table 3 - Key regulatory elements for hospitals

Federal	State	Private
Centers for Medicare & Medicaid Services • Rules for Medicare participation • Structure of Medicare reimbursement (DRGs) • Open access for emergency rooms (EMTALA) • Clinical laboratory quality (CLIA) • Medicare Hospital Compare website • Penalties for quality lapses	Department of Health • Licensure • Certificate-of-need programs • Data reporting • Patient Safety Authorities	Hospital industry • Joint Commission
Internal Revenue Service • Tax exemption requirements for nonprofit hospitals • Limits on self-dealing	Department of Aging • Oversight of nursing homes	Insurance companies • Inclusion in networks • Review of expensive procedures
Non-discrimination rules • Americans with Disabilities Act • Civil Rights Act		

surance company through the Employee Retirement Income Security Act (ERISA).[44,45] In 1985, the Comprehensive Omnibus Budget Reconciliation Act (COBRA) gave workers the right to continue their employer coverage for up to 18 months after the end of employment.

The most significant federal regulatory intervention is the ACA, which reformed the individual market in which consumers purchase coverage directly from insurance companies. It created online exchanges through which policies are sold subject to regulations, including a requirement that companies offer coverage and set premiums without regard to an applicant's health status, and it provides subsidies for purchasing policies for those with low incomes. It also requires that all large employers offer coverage to their workers. To avoid the risk that people will wait until they become sick before purchasing coverage, the law includes a mandate that all Americans maintain health coverage in some form or pay a penalty. Other ACA regulations prohibit annual and lifetime limits on coverage and rescission of policies for reasons other than fraud by the applicant. All private health insurance, including coverage provided by employers, must cover ten "essential health benefits," including basic forms of treatment and preventive care.[46]

Private regulation of health insurance is limited. The primary form is a rating of managed care plans by a nonprofit organization controlled by the industry known as the National Committee on Quality Assurance (NCQA).[47]However, review by the NCQA is optional, and plans can operate without it.

Table 4 - Key regulatory elements for health care finance

Federal	State	Private
Center for Medicare & Medicaid Services • Administration of Medicaid • Administration of Medicaid	Insurance department • Business of insurance (coverage, reserves)	Insurance industry • National Committee on Quality Assurance
Federal Department of Labor • Self-insured employer health plans (ERISA) • Employer coverage continuation rules (COBRA)	Department of Welfare • Medicaid	
	Department of Aging • Pharmaceutical assistance programs for the elderly	
	Department of Health • Managed care plans (health care aspects)	

Regulation of medical products

The regulatory structure for drugs and medical devices is more straightforward than it is for the other health care sectors (table 5). Most oversight is by the federal government under its constitutional authority to regulate commerce among the states. Regulation at the state level is confined primarily to licensing pharmacists and pharmacies and determining the kinds of health care professionals who have prescribing authority.

The primary federal authority for regulating drugs and devices is the Food and Drug Administration (FDA), which oversees their testing, sale and marketing. The agency regulates all phases of testing from preclinical tests on animals to clinical trials on patients. When testing is complete, the FDA reviews all data generated on safety and efficacy and decides whether the product may be marketed. It also reviews and approves claims that manufacturers make for products and specifies warnings of possible adverse effects that must be included in labeling and promotional materials. After marketing has begun, it reviews ongoing reports of adverse events experienced by patients.[48]

Once a drug has been approved, FDA oversight of its use in clinical practice is limited. Physicians may legally prescribe an approved drug for any purpose, even one that has not been reviewed by the FDA, a practice known as "off-label prescribing." The agency has issued rules restricting promotion of drugs for unapproved uses, but it does not have authority to regulate the way physicians actually prescribe them.[49]

For drugs sold over-the-counter directly to patients, another agency, the Federal Trade Commission (FTC), oversees marketing and promotion. It has broad power to protect consumers from unfair trade practices, including false advertising. The agency can levy fines and order companies to cease making claims that are not substantiated.[50,51]

A third agency, the Drug Enforcement Administration (DEA), regulates the sale, marketing and prescribing of narcotics and other controlled substances. Physicians must obtain a license from the DEA before prescribing them. The agency places drugs on schedules according to dangerousness and sets conditions for prescribing drugs on each schedule. It also tracks prescribing patterns for controlled substances.[52]

No drug or device can enter the testing process before a long course of ba-

sic biomedical research has laid the foundation for its development. The major source of funding for this research is the National Institutes of Health (NIH), the largest funder of biomedical research in the world with an annual budget that exceeds $30 billion.[53] NIH funding has played a major role in the development of almost every new drug over the past half century.[54,55] When human subjects are involved in research, the agency also oversees their safety through a system of Institutional Review Boards at each organization where the research is conducted.[56]

Medical products are also subject to intellectual property regulation to protect the interests of their manufacturers. Patents, which are issued by the federal Patent and Trademark Office, protect new drugs and devices from competition for 20 years from the date of filing, however premarket testing commonly consumes a large portion of this time.[57] A complex set of rules, established by the Drug Price Competition and Patent Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), governs the introduction of generic copies of drugs when their patents expire.[58,59]

Pharmaceutical companies also face indirect regulation by the private insurance plans that pay for their products. Each plan maintains a formulary that lists the drugs eligible for reimbursement and the medical conditions for which they may be prescribed. For a drug to be included on a formulary, the manufacturer usually must demonstrate that its benefits are commensurate with the cost.[60] The actual purchase of drugs that are reimbursed under insurance plans is often accomplished by pharmacy benefit managers, which negotiate over prices based on a drug's clinical value and the availability of substitutes.[61]

Table 5 - Key regulatory elements for medical products

Federal	State	Private
Department of Health and Human Services • Food and Drug Administration • National Institutes of Health	Department of Health • Regulation of pharmacies	Insurance companies • Formulary selection
Department of Justice • Drug Enforcement Administration	Medical and professional boards • Licensure of pharmacists • Licensure of physicians and other prescribing clinicians	Pharmacy Benefit Managers • Price negotiation
Department of Commerce • Patent and Trademark Office		
Federal Trade Commission		

Compromise in American health care regulation: a public-private partnership

It is common for Americans to view regulation as a force that is adverse to private industry. They see it as necessary to curb some abuses but also as stifling growth and innovation. For example, a 2007 commentary in *The Economist* magazine referred to health care regulation as "a massive drag on the American economy" that amounted to "a $169 billion hidden tax."[62]

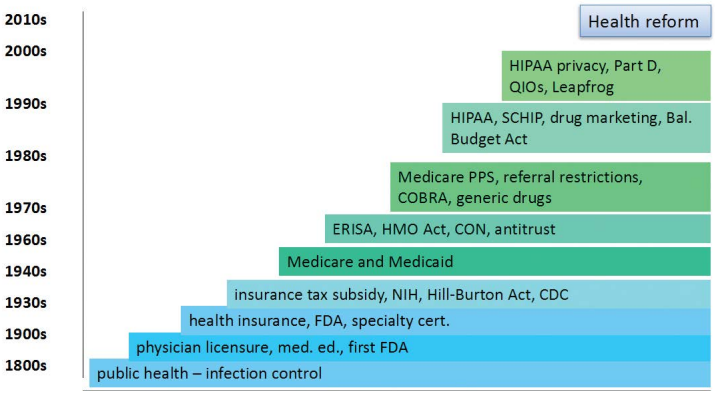
However, the ultimate goals of regulators and regulated may not actually conflict. They may be more similar to partners in a common enterprise than adversaries. In fact, regulation can be seen as an essential force that enables private markets to thrive.

Over the last 200 years, American health care regulation has grown dramatically in amount and scope, steadily expanding to address new concerns with additional programs (figure 1). If this growth has stifled the health care system's vitality, it would be difficult to tell from its performance. Between 1960 and 2008, the system grew from 5.2 percent of gross domestic product to more than 16.2 percent and spending per capita rose from $148 to $7,681.[63] For the past several decades, Americans have spent more on health care than citizens of any other country in the world.[64,65]

As the health care system has grown, the portion financed by public spending has also risen, from 24.5 percent in 1960 to 47.3 percent in 2008, and much of this funding has brought with it new layers of regulation.[63] However, this expansion of government intervention has not crowded out the private sector. Private health care spending grew just as dramatically over the same period from $111 per capita in 1960 to $3,788 in 2006.[63] The private health care industry is today one of the most profitable in the country, with an average profit margin of 15.4 percent.[66]

The Medicare program has been an especially strong catalyst for growth. The pipeline of future physicians depends on its funding of residency and fellowship programs at hospitals ($9.5 billion in 2010).[67] Its coverage of services provided by many kinds of ancillary facilities, such as home health agencies, kidney

Figure 1 - Historical expansion of health care regulation



dialysis centers, outpatient physical therapy clinics, ambulatory surgery centers and hospices, has coincided with a similar explosion in their numbers. (Between 1980 and 2015, the number of home health agencies increased from 2,924 to 12,149, of renal dialysis facilities from 999 to 6,558, of outpatient physician therapy centers from 419 to 2,130, of ambulatory surgery centers from 0 to 5,470, and of hospices from 0 to 4,302.[68]) As the single largest source of reimbursement for hospital care, it has transformed that industry and served as the financial foundation for the emergence of two of its pillars: national for-profit chains and academic medical centers. (The number of for-profit hospitals grew from 775 in 1975 to 998 in 2009, and the number of beds increased from 73,495 to 122,071.[69,70])

What Medicare has done for hospitals, NIH has done for pharmaceutical companies. As NIH spending on biomedical research has grown over the past 70 years, the pharmaceutical industry has become one of the most profitable in the country, with profit margins often in the range of 20 percent.[71] Those companies have produced a steady stream of new drugs that include many treatments once thought impossible.[72] Rather than crowding out private research, increases in NIH funding have coincided with even faster growth in industry spending, which now exceeds that of NIH.[72(p8)]

The expansion of American health care benefits not only investors and patients, but the overall economy, as well. Health care is now among the largest employers in the United States, providing more than ten percent of all nonfarm jobs, up from just three percent in 1958.[73] The expansion of health care employment over the past several decades has outpaced that of all other industries and has proven impervious to economic downturns, continuing even during the Great Recession of 2008.[74]

The synergy between regulators and the health care industry also has a significant downside. It has produced the most expensive health system in the world, one that spends almost twice the average of all OECD countries.[2] Moreover, as the private sector has expanded, it has applied its growing resources to efforts to influence the government that supports it, seeking to maintain and expand the programs on which it relies by spending more on lobbying than any other.[75] The resulting spending growth has helped make the system bloated and inefficient. However, it is also a system that drives innovation and produces a constant stream of medical advances.

Conclusion

The American health care system and its regulators have together produced a massive and vibrant enterprise. Private industry provides goods and services, and regulation by public and private bodies offers needed stability and support. Not all regulatory programs are efficient or effective, but comprehensive oversight and government support are as essential to the system's success as the activities of the organizations and professionals they oversee.

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