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A TAXONOMY OF AMERICAN HEALTH CARE REGULATION: IMPLICATIONS FOR HEALTH REFORM

by ROBERT I. FIELD*

INTRODUCTION

Health care is one of America's largest industries and is among the most highly regulated. It represents sixteen percent of the economy, a number that is expected to rise to over twenty percent in the next decade.[1] All levels of government as well as numerous private organizations oversee aspects of this huge enterprise in ways that sometimes complement one another but often conflict. The result is a regulatory system of almost bewildering complexity.

All proposals at both the state and federal levels to change the way health care is delivered and financed rely on regulatory structures to take effect. Therefore, any effort to reform the health care system has to be implemented through regulation. Regulation may include both government programs overseen by administrative agencies and private regulatory initiatives conducted through nonprofit organizations that issue guidelines and criteria for clinical behavior.

Because of its central role in effectuating reform, a conceptual understanding of the nature of American health care regulation is essential to assessing the prospects of reform initiatives. Over the course of the past century, different paradigms of regulation have emerged that govern various aspects of the system.[2] In none of them does a single regulatory authority function in isolation, and in all cases, regulators at various levels interact in a dynamic process. For reform to succeed, it will almost certainly have to fit into this model.

This Article will present a taxonomy of health care regulation according to the roles of different regulatory authorities. The basis for the taxonomy will first be presented by defining the nature of regulation and briefly surveying the historical sweep of regulatory programs. The taxonomy will then be applied to assess

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1. Estimates for the total cost of health care in the United States are derived by the Centers for Medicare & Medicaid Services. *See* Centers for Medicare & Medicaid Services, National Health Expenditure Data, http://www.cms.hhs.gov/NationalHealthExpendData/ (last visited Apr. 15, 2008) (outlining up-to-date health care information and statistics); *see also* HENRY J. KAISER FAMILY FOUND., HEALTH CARE COSTS: A PRIMER 2 (2007), *available at* http://www.kff.org/insurance/upload/7670.pdf (presenting a more complete analysis of the rising trend in health care costs).

2. *See* ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION AND COMPROMISE 4 (2007) (noting that "the evolution of health care regulation over the past century reflects the changing balance of the three core objectives" of a well-functioning health care system: acceptable quality of care, widespread access to care, and affordable care).

proposals for health reform in general and for proposals to reform the system specifically at the state and at the federal levels. Finally, it will end with observations on key drivers that will determine the success of reform initiatives.

I. REFORM AND REGULATION

In its broadest sense, regulation is the external direction of private activity. Webster's Dictionary defines the word "regulate" as "to bring under control of law or constituted authority" or "to bring order, method, or uniformity to."[3] In health care, a broad range of activities are brought under the control of governmental bodies and of private standard-setters. The goal in doing so is to bring order and uniformity in the interests of enhancing and maintaining the overall system.

Efforts to improve the health care system through regulatory reform invariably focus on one of three goals.[4] They seek either to promote quality, to insure access, or to control costs. The key challenge for policy makers is that the goals compete with one another. It is always possible to promote one of them, but the outcome will inevitably impair one or both of the others. For example, health care quality could be enhanced through a number of simple steps, such as adding more years of training for clinicians or more layers of review of hospital operations.[5] However, any such steps would add costs, which, in turn, might necessitate restrictions on access.[6] Similarly, cost-cutting measures such as reductions in provider reimbursement would likely reduce the quality of care.[7] The conflict in goals continually confronts regulators, leading to increasing layers of structural complexity as each reform necessitates new ones to maintain balance in the system.[8]

The regulators who implement these programs function in a broad range of settings. Government regulators may operate within agencies at the federal, state, or local levels. In addition, a significant source of regulation of the health care system operates in the private sphere. Among the most influential of these private bodies are boards and commissions composed of members of the regulated organizations or professions, themselves.[9] For example, the most intensive review of hospital operations is conducted not by state licensure authorities but by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a private nonprofit organization that accredits its own member hospitals.[10] Physicians are acknowledged as members of medical specialties not through the licensure process but by private boards composed of fellow physicians in those specialties. Managed care organizations achieve quality certification through the National Committee on

3. WEBSTER'S NEW COLLEGIATE DICTIONARY 992 (9th ed. 1990).

4. *See* WILLIAM L. KISSICK, MEDICINE'S DILEMMAS 1-10 (1994) (discussing the three health care goals and their interplay).

5. *Id.*

6. *Id.* at 2.

7. *Id.* at 1-10.

8. *See generally id.* (discussing how the three goals interact).

9. FIELD, *supra* note 2, at 43.

10. *Id.*

Quality Assurance (NCQA), a private body controlled by insurance companies and employers.[11]

The functions of regulatory bodies can be grouped into four broad categories. There are rulemaking activities through which they set standards. In health care, these determine, for example, the criteria for achieving professional or institutional licensure and for conducting ongoing practices and operations.[12] There are adjudications through which they resolve disputes. These may involve enforcement actions or license denials or restrictions.[13] There are administrative activities, such as the management of public hospitals. Finally, there is the role of administering funding, as in the implementation of the Medicare and Medicaid programs.[14]

The regulatory system for health care reflects the interaction of these bodies and their functions to a greater extent than the isolated activities of any of them. Health care reform, in whatever form it may take, will have to be implemented through this intertwined system. Therefore, the underlying dynamics of regulatory interactions will be key factors in determining the success or failure or any reform initiatives.

II. PROPOSED VIEW OF REGULATORY STRUCTURE

The regulation of health care is commonly viewed in a broad sense as a contest between those imposing regulation and those subject to their authority. Along these lines, various commentators have viewed regulation as an external cost imposed on private industry, as a burden on private innovation, and as a form of taxation.[15] This concept of the roles of regulators and of those they regulate divides the two into distinct spheres with few common functions, interests, or goals.

The underlying reality of health care regulation, however, is quite different. In the complex web of authorities, the interests of the regulators and of the regulated frequently intersect. The concept of a dichotomy between the two is a distortion of the intricate interplay that actually characterizes the regulatory enterprise. Rather than representing an external constraint on private activity, the regulation of health care can more accurately be described as a collaboration between a broad range of

11. *Id.* at 10.

12. *See, e.g.*, *id.* at 11-12 (discussing the role of regulatory bodies in devising standards for medical practice and licensing medical professionals and institutions).

13. *See, e.g.*, *id.* at 12, 20 (noting the role of regulatory bodies in enforcing standards for medical practice by granting or denying licenses).

14. *See, e.g.*, *id.* at 58 ("A significant form of economic regulation . . . is imposed through the Medicare payment structure.").

15. *See* MICHAEL F. CANNON & MICHAEL D. TANNER, HEALTHY COMPETITION: WHAT'S HOLDING BACK HEALTH CARE AND HOW TO FREE IT 3-6 (2005) (promoting competition and discussing the view of regulation as an external impediment to innovation in health care); *see also* RICHARD A. EPSTEIN, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 66-68 (2006) (examining the view of regulation as a burden on private innovation); CHRISTOPHER J. CONOVER, CATO POLICY ANALYSIS NO. 527, HEALTH CARE REGULATION: A $169 BILLION HIDDEN TAX 9 (2004), *available at* http://www.cato.org/pubs/pas/pa527.pdf (discussing the view of regulation as a form of taxation on private industry).

public and private players that to a significant degree has actually helped to unleash the entrepreneurial potential of America's health care industry.[16]

Health care regulation in America, therefore, is most accurately characterized as a complex public-private partnership that can nurture as well as restrict innovation.[17] Its layered structure in part reflects America's federalist system of government and in part an American value of protecting the rights of all affected parties in any governmental proceeding. Virtually all regulatory programs are characterized by competition and collaboration between public and private entities. To design successful new programs, whether they embody incremental changes or fundamental reform, it is necessary to understand this dynamic.

III. HISTORICAL GROWTH OF HEALTH CARE REGULATION

In its historical sweep, American health care regulation is a series of programs layered one on top of another over the course of the past 150 years. The earliest programs were created in the mid to late nineteenth century and primarily addressed public health concerns.[18] With the discovery of the link between germs and disease, government policy focused on breaking the chain of transmission. Early programs implemented measures such as improved sanitation, provision of clean drinking water, quarantine of patients with infectious diseases, vaccination in the face of epidemics, and screening of immigrants for tuberculosis.[19] Most of these programs, with the exception of controls on immigration, were instituted at the local level.

With the start of the twentieth century, public policy turned its attention to the quality of health care providers. For example, licensure laws for physicians were enacted in every state that implemented oversight under the direction of boards of medicine.[20] Private organizations, often in collaboration with the medical profession's umbrella professional association, the American Medical Association (AMA), developed systems to accredit medical schools and to prepare the tests that determine eligibility for licensure. Similar regulatory schemes were implemented over the course of the twentieth century for many allied health professions.[21] In

16. FIELD, *supra* note 2, at 17-18 (noting the effects of a complex regulatory scheme, combining public and private entities, on the American health care system).

17. *See generally id.* at 3 (describing health care regulation as an intricate interaction of public and private regulatory bodies).

18. *See* Elizabeth Fee & Theodore M. Brown, *The Unfulfilled Promise of Public Health: Déjà Vu All Over Again*, HEALTH AFF., Nov./Dec. 2002, at 31, 32-35 (discussing early public health programs); *see also* GEORGE ROSEN, A HISTORY OF PUBLIC HEALTH 246-48 (1958) (providing a history of early public health programs motivated in part by industrialization and the resulting need for increased sanitation).

19. *See, e.g.*, ROSEN, *supra* note 18, at 246-47 (noting the New York City Health Department's role as an early public health agency).

20. *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 102-07 (1982) (discussing the history of physician licensure).

21. *See* INST. OF MED., ALLIED HEALTH SERVICES: AVOIDING CRISES 235-58 (1989) (reviewing the history of the regulation of allied health professionals).

1906, Congress passed the first law regulating the safety of pharmaceutical products and established the Food and Drug Administration (FDA).[22]

During the 1930s, the first systematic mechanisms for financing health care were developed.[23] The initial impetus came from the industry itself, with hospitals forming the first Blue Cross plan in Dallas, Texas in 1929 and subsequent plans over the course of the next decade.[24] Physicians devised the first Blue Shield plan to cover professional services in 1939 in Sacramento, California.[25] Health insurance received a significant regulatory boost during World War II from the federal War Labor Board, which oversaw a general wartime freeze on wages.[26] In 1943, the Board permitted an exception to the freeze for benefits, such as employer-paid insurance, which it considered to be distinct from wages.[27] After the War, the Internal Revenue Service (IRS) extended this reasoning to exclude health insurance benefits from wages that were subject to income tax, and this position was legislatively codified by Congress in amendments to the Internal Revenue Code enacted in 1954.[28]

During the 1930s and 1940s, several other regulatory initiatives took shape that later promoted substantial growth in the industry. In 1938, the FDA gained new authority to review the safety of new drugs before they reached the market.[29] This step ultimately encouraged heightened public confidence in pharmaceuticals. In the early 1930s, Congress created the National Institute of Health (NIH), which grew into a set of institutes that supported scientists who made countless basic biomedical discoveries.[30] In 1946, Congress passed the Hill-Burton Act, which injected billions of dollars into the construction and expansion of hospitals over the next 30 years.[31]

The movement to enhance access to health care reached its high point in the 1960s with the passage of Medicare and Medicaid.[32] These huge programs

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22. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

23. *See* STARR, *supra* note 20, at 266-95 (discussing how the Depression revived the social insurance movement).

24. *Id.* at 295.

25. *Id.* at 307.

26. *Id.* at 311.

27. *See id.* ("In 1942, the War Labor Board decided that fringe benefits up to 5 percent of wages would not be considered inflationary . . . .").

28. 26 U.S.C. § 3121(a)(2) (2006).

29. Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301-397 (2006); *see id.* § 355 (requiring approval of application before a drug is introduced into commerce).

30. *See* VICTORIA A. HARDEN, INVENTING THE NIH: FEDERAL BIOMEDICAL RESEARCH POLICY, 1887-1937 (1986) (reviewing the history of NIH); *see also* Nat'l Insts. of Health, The NIH Almanac – Historical Data, http://www.nih.gov/about/almanac/historical/chronology_of_events.htm (last visited Apr. 15, 2008) (describing the creation of the National Institute of Health in the 1930s).

31. Hospital Survey and Construction Act of 1946, 42 U.S.C. §§ 291 to 291o-1 (2000 & Supp. IV); *see also* STARR, *supra* note 20, at 350 (noting that by 1971, 3.7 billion dollars had been appropriated for hospital construction under the Act).

32. *See* Earl D. Hoffman, Barbara S. Klees & Catherine A. Curtis, *Overview of the Medicare and Medicaid Programs*, HEALTH CARE FINANCING REV., Fall 2000, at 175 ("Congress passed legislation in 1965 establishing the Medicare and Medicaid programs as Title XVIII and Title XIX, respectively, of the Social Security Act.").

guaranteed financial coverage of health care expenses for the elderly and for certain categories of the poor. Their implementation required large new regulatory structures that served over time to shape many aspects of the provision of care.[33]

During the late twentieth century, the predominant focus of new regulatory programs was on containing costs. For example, federal legislation required each state to implement a certificate-of-need program to limit hospital expansion under the theory that excess capacity was leading providers to induce excess demand.[34] Medicare tried to rein in spending through several strategies.[35] Physicians were subjected to peer review to assess patterns of hospital utilization through Professional Standards Review Organizations (PSROs).[36] Anti-kickback rules outlawed payments in return for the referral of patients in order to reduce unnecessary utilization.[37] Most significantly, the system for reimbursing hospitals was changed to a prospective one that based payments on a fee set in advance according to the patient's diagnosis rather than on the cost of services actually provided.[38]

Recent regulatory programs have addressed a range of concerns. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), rules were implemented to safeguard the privacy of patient medical information.[39] The Medicare Prescription Drug, Improvement and Modernization Act (MMA) created a new program within Medicare to cover part of the cost of prescription drugs.[40] Various other federal programs addressed pharmaceutical marketing practices, health insurance for children, and collection of data on medical errors.[41]

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33. *See id.* at 84 (discussing the structure and history of the Medicare and Medicaid programs); *see also* Richard A. Culbertson & Philip R. Lee, *Medicare and Physician Autonomy*, HEALTH CARE FINANCING REV., Winter 1996, at 115, 121 (reviewing some of the effects of the implementation of Medicare on the provision of care).

34. National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (codified in scattered sections of 42 U.S.C.).

35. *See* Anita J. Bhatia, Sheila Blackstock, Rachel Nelson & Terry S. Ng, *Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement*, HEALTH CARE FINANCING REV., Fall 2000, at 69 ("Soon after the enactment of the Medicare program in 1965, it became clear that fulfilling the mandate of providing health care security to Medicare beneficiaries would require assurances that funds were used effectively and that beneficiaries received care consistent with medical quality standards.").

36. *See* INST. OF MED., ACCESS TO MEDICAL REVIEW DATA: DISCLOSURE POLICY FOR PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS (1982) (presenting background on the PSRO program); *see also* Bhatia et al., *supra* note 35, (reviewing the development, successes, and future directions of the Professional Review Organization (PRO) program, the successor to PSROs).

37. The statutory prohibition against the exchange of remuneration in return for the referral of Medicare patients was enacted as part of amendments to the Medicare Act in 1977. 42 U.S.C. §§ 1320a-7b (2006).

38. This system is known as diagnosis-related groups (DRGs). *See generally* Judith J. Baker, *Medicare Payment System for Hospital Inpatients Diagnosis-Related Groups*, J. OF HEALTH CARE FIN., Spring 2002, at 1, 1-13 (discussing the implementation of the DRG system).

39. 42 U.S.C. §§ 300gg-1 to -92 (2006); *see also* 45 C.F.R. § 160.203 (2008) (implementing HIPAA's privacy provisions, commonly known as the "Privacy Rule").

40. Pub. L. No. 108-73, 117 Stat. 2066 (2003) (codified at 42 U.S.C. § 1395 (2006)).

41. *See, e.g.*, Food and Drug Administration Modernization Act, Pub. L. No. 105-15, 111 Stat. 2296 (1997) (addressing pharmaceutical marketing practices regarding uses of drugs for purposes other than

A handful of programs have disappeared over the years, but for the most part, the set of regulatory schemes that was brought into being over the past century has remained in place.[42] Most new programs have supplemented, rather than replaced, those that came before. For example, the oversight of physicians began with the creation of medical boards to issue licenses as a basic control of quality, but licensure today is only the first regulatory hurdle to establishing a functioning practice.[43] Physicians must now complete residencies that are funded and regulated by Medicare, achieve certification by a specialty board, gain clinical privileges from a hospital, meet criteria to participate in Medicare, and join the network of a managed care organization.[44] The regulation of drugs began in earnest with Congress' grant of authority to the FDA to fine manufacturers of adulterated products and to order such products withdrawn from the market.[45] Today, new drugs must undergo years of pre-market testing according to FDA-specified protocols to demonstrate both safety and efficacy.[46] Manufacturers must also report adverse drug events after marketing, comply with numerous restrictions on marketing activities, label and promote drugs only in compliance with FDA directives, and gain acceptance of their drugs on managed care formularies.[47]

In this manner, new regulatory programs have added additional levels of complexity. Every player in the system must navigate a maze of layers in order to function. Nevertheless, the health care industry has grown and thrived through this

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those approved by the FDA); John K. Igelhart, *The Battle over SCHIP*, 357 NEW ENG. J. MED. 957, 957-60 (2007) (discussing the State Children's Health Insurance Program (SCHIP), which addressed health insurance for children of families with incomes that are low but above the threshold for Medicaid). Collection and analysis of data on medical errors has, for the most part, been promoted at the state level. *See* Medical Care Availability and Reduction of Error Act, 40 PA. STAT. ANN. § 1303.303 (West 2008) (representing one of the most aggressive state programs establishing a Patient Safety Authority to collect and analyze information on mistakes made in Pennsylvania hospitals).

42. Two examples of health care regulatory programs that have been repealed are an expansion of Medicare to cover catastrophic expenses and the federal mandate that states administer certificate-of-need (CON) laws. The catastrophic coverage provisions were enacted in 1988 and repealed the next year after controversy over accompanying premiums increases. *See* RICHARD HIMELFARB, CATASTROPHIC POLITICS: THE RISE AND FALL OF THE MEDICARE CATASTROPHIC COVERAGE ACT OF 1988 (1995) (providing a history of this program); *see also* Christine L. Day, *Older Americans' Attitudes Toward the Medicare Catastrophic Coverage Act of 1988*, 55 THE J. OF POL. 167, 177 (1993). CON laws grew out of state health planning programs, which were encouraged by the Comprehensive Health Planning and Services Act of 1966, 42 U.S.C. § 246 (2000) (allocating funds to states for the development of health planning programs), and mandated by the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. § 300k-n (2000)). Congress permitted the mandate to lapse in 1986, and about a third of the states abandoned their programs in response. *See* AM. HEALTH PLANNING ASS'N, NATIONAL DIRECTORY OF STATE CERTIFICATE OF NEED PROGRAMS PLANNING AGENCIES, WASHINGTON, D.C. (2007), *available at* http://www.ahpanet.org/files/ahpa%202007%20directory%20brochure%20B.pdf (listing the states that retain CON programs).

43. *See* FIELD, *supra* note 2, at 20-21 (discussing licensure of physicians).

44. *See id.* at 21-40 (discussing additional steps taken by both public and private entities to regulate physicians).

45. *See id.* at 118-27 (explaining the development of the FDA).

46. *See id.* at 114-40 (discussing the range of regulatory requirements that apply to the sale and marketing of drugs).

47. *Id.*

relentless regulatory expansion. Health care reform, whether at the state or federal level, will add yet additional layers, but as with past efforts, well-crafted reform programs could enhance the industry's overall functioning.

IV. PARADIGMS OF HEALTH CARE REGULATION

The division of authority within spheres of regulation seems to be, on its surface, chaotic. Different bodies operate without clear coordination. They arose at various times in response to changing policy concerns. They respond to different constituencies, some political and some comprised of the regulated entities, themselves.

To make sense of this landscape, the breadth of regulatory mechanisms and interactions can be understood according to an underlying taxonomy that divides programs into three paradigms. The first places primary authority at the state level, as in the example of the licensure of physicians, but with coordination at the federal level and supplementary oversight through private organizations.[48] The second places primary authority at the federal level, as in the example of the regulation of new drugs, but with a supplementary private role.[49] The third revolves around the federal spending power.[50] It places primary authority in a federal agency that injects funding into an aspect of health care but with substantial regulatory restrictions, as in the example of the Medicare program.[51] Of particular significance, the funds are provided to private entities whose operational decisions determine the actual implementation of the programs. This last paradigm has played an especially important role in nurturing and guiding the growth of American health care, and it represents the most promising approach to achieving substantial reform.

A. Paradigm 1: State Primacy

Many of the earliest forms of health care regulation assigned a primary role to the states. These included the licensure of physicians,[52] the licensure of allied health professionals such as nurses and pharmacists,[53] the licensure of hospitals,[54] the licensure of insurance companies that cover the cost of health care services, and basic public health measures, such as sanitation, quarantine, and vaccination.[55] These areas of regulatory concern were initially conceived of as falling outside of

48. *See id.* at 9 ("The states were the original locus of regulatory activity . . . .").

49. *See* FIELD, *supra* note 2, at 10 ("[T]he most significant player in health care regulation today is the federal government . . . . The provision of health care may be local, but it is now unquestionably a national concern.").

50. *See id.* (explaining that federal programs are the largest source of payment for health care).

51. *See id.* at 10-15 (providing a brief background on health care regulatory agencies and programs).

52. *See id.* at 22- 24 (describing state licensing of medical professionals).

53. *Id.*

54. *See id.* at 42 ("Hospitals and other health care institutions are licensed by the state in which they are located.").

55. *See* FIELD, *supra* note 2, at 142, 144, 164-67 (explaining that states took early steps to fight infectious diseases and inspect food and describing state public health departments).

interstate commerce, making state jurisdiction appropriate. In some cases, regulation was instigated by the regulated entities, themselves, such as the licensure of physicians, which was spearheaded by the AMA, and the licensure of several kinds of allied health professionals, including pharmacists and psychologists.[56]

No aspect of health care is purely local in its effect, and the initial locus of regulatory authority within the states became difficult to maintain over time. Physicians move between states and may practice simultaneously in more than one. Scandals have arisen over the years involving errant physicians who lost licensure in one state only to apply and gain it back in another one.[57] The National Practitioner Data Bank (NPDB), established by federal legislation in 1986, enables each state medical board to check on the history of applicants.[58] Physician competence is also assessed across states through uniform testing and certification.[59] Because standards of care are recognized on a national, rather than local, level, licensure examinations, which are accepted by all state medical boards, are administered nationally, and specialty certification is conducted by national societies and recognized throughout the country.[60]

Like physicians, hospitals are licensed by the states. However, this requirement represents only a preliminary step in the oversight process. Licensure is supplemented by accreditation, which is essential to public acceptance of quality and to participation in most private and governmental reimbursement programs, and is conducted on a uniform national basis by the JCAHO.[61]

Layered over this system of state and private oversight are numerous sets of federal rules. Through the Medicare program, the federal Centers for Medicare and Medicaid Services (CMS) requires that hospitals assess and stabilize patients who enter their emergency rooms without regard to ability to pay.[62] Hospitals that operate on a tax-exempt basis, including the majority of those in the United States, are subject to additional oversight by the IRS.[63] The rules of this agency are intended to insure that the institutions it recognizes as charitable serve an actual

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56. *See id.* at 20-22 (discussing the role the AMA played in establishing educational and licensing requirements for physicians).

57. *See, e.g.*, Donald Janson, *Doctor Suspended in Hepatitis Dispute Is Practicing in Pennsylvania: Agreement by Board Questioned in Drug's Role*, N.Y. TIMES, Jan. 14, 1977, at 43 (reporting how a physician, whose license was suspended in New Jersey, gained a new one in Pennsylvania).

58. Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-11152 (2006).

59. For example, the United States Medical Licensing Examination is a professional examination sponsored by the Federation of State Medical Boards and the National Board of Medical Examiners. Medical doctors are required to pass it before being permitted to practice medicine in the United States. United States Medical Licensing Examination, About USMLE, http://www.usmle.org/General_Information/general_information_about.html (last visited Apr. 15, 2008).

60. *See, e.g.*, Composite State Board of Medical Examiners of the State of Georgia, Licensure Requirements: All Professions, http://www.medicalboard.state.ga.us/licensure_rr.html (last visited Apr. 15, 2008) (explaining that the state of Georgia accepts the nationally administered licensure examination).

61. Some states accept JCAHO accreditation in lieu of licensure review, which eliminates one step in the regulatory process for hospitals.

62. Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd.

63. *See* Rev. Rul. 69-545, 1969-2 C.B. 117 (insuring that institutions recognized as charitable are serving a community purpose).

community purpose through the provision of indigent care and similar activities.[64] Other federal rules govern the health and safety of hospital employees and the operation of clinical laboratories.[65]

Insurance companies are regulated by the states, and this locus of authority is explicitly recognized by the federal McCarran-Ferguson Act.[66] State jurisdiction applies to health insurance provided by nonprofit Blue Cross and Blue Shield plans and by for-profit commercial insurers.[67] However, insurance coverage that is provided through employment, as is the preponderance of nongovernmental coverage, is exempted from most state oversight by the Employee Retirement Income Security Act of 1974 (ERISA) and is subject to a looser set of rules administered by the federal Department of Labor.[68] Coverage that is self-insured by employers is entirely exempted by ERISA from state-level rules.[69] Moreover, all health insurance policies, whether governed by state regulation, ERISA, or a combination, must comply with all of the following: a variety of federal mandates, including continuation of coverage after employment under the Comprehensive Omnibus Budget Reconciliation Act of 1986 (COBRA),[70] limits on use of pre-existing conditions in underwriting under HIPAA,[71] and minimum coverage of reconstructive surgery after mastectomies and of certain other services.[72]

The regulation of public health represents a particularly complex interaction of oversight authorities. Many of the most basic functions, such as inspection of restaurants, oversight of sanitation, and investigation of disease outbreaks, are conducted by local authorities at the municipal and county levels.[73] Their activities are supplemented, coordinated, and often funded, by the states. However, diseases are rarely contained within local areas, and broader responses are often needed. Such responses are provided by the federal Centers for Disease Control and Prevention (CDC), which coordinates public health data on a national level, issues guidelines for disease prevention and response, and assists state and local

64. *Id.*

65. For example, the health and safety of health care workers is regulated by the Occupational Safety and Health Administration under the Occupational Safety and Health Act, 29 U.S.C. § 651 (1970), and the operations of clinical laboratories are regulated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments, 42 U.S.C. § 201, § 263a (2000).

66. McCarran-Ferguson Act, 15 U.S.C. §§ 1011-1014 (2006).

67. *Id.*

68. Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1144 (2006).

69. *Id.*

70. Comprehensive Omnibus Budget Reconciliation Act of 1986, 29 U.S.C. §§ 1161-1168 (2006).

71. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., 42 U.S.C.).

72. Coverage of reconstructive surgery after mastectomies is mandated by the Women's Health and Cancer Rights Act of 1998, 29 U.S.C. § 1185b (2006). Other federal laws that mandate specific kinds of coverage under private health insurance policies include the Mental Health Parity Act of 1996, 29 U.S.C. § 1185a (2006) and the Newborns' and Mothers' Health Protection Act of 1996, 29 U.S.C. § 1185 (2006).

73. *See* Geurin v. City of Little Rock, 155 S.W.2d 719, 721 (Ark. 1941) (holding that the preservation of the health of the population is uniformly recognized as an important municipal function).

authorities in disease investigations.[74] National public health efforts are also supplemented by private foundations that are concerned with specific diseases and by patient advocacy groups.[75]

B. Paradigm 2: Federal Primacy

For the most part, the federal government avoided taking the lead in regulating health care until the middle of the twentieth century.[76] The exception was oversight of the safety of foods and drugs, with the passage in 1906 of the federal Meat Inspection Act,[77] which gave the Department of Agriculture authority to regulate contamination of meat products, and the federal Pure Food and Drug Act,[78] which created the FDA to regulate the safety of drugs. However, with regard to drug safety, the powers of the FDA were limited to post-market regulation in this initial drug safety law.

Congress substantially expanded the federal role in regulating drug safety in 1938, when it passed the Food, Drug, and Cosmetic Act.[79] The regulatory scheme implemented in response to this law serves as the archetypical example of the federal primacy paradigm. Under it, the scope of government oversight grew significantly, as the FDA was granted authority to review the safety of new drugs before they reached the market.[80] To this end, the agency promulgated regulations that prescribe in considerable detail the kinds of tests that must be performed to establish safety, including the nature of each phase of investigation involving human subjects.[81] The FDA's regulatory scheme also includes oversight of all labeling and marketing of prescription drugs and continued surveillance after marketing has begun.[82] In 1962, Congress expanded the FDA's scope of authority yet again by adding proof of a drug's efficacy as an additional requirement for marketing approval.[83]

As central as it is to public protection, the FDA approval process is, nevertheless, only one part of the regulatory maze that a manufacturer must

74. *See generally* Paul Cotton, *CDC Nears Close of First Half-Century*, 263 J. AM. MED. ASS'N, 2579-80 (1990) (discussing the history of the CDC).

75. For example, the American Heart Association and the American Cancer Society fund research and public education concerning diseases within their scopes of interest and advocate for increased government funding.

76. *See* FIELD, *supra* note 2, at 32-36 (discussing the growth of federal involvement in health care regulation and the conflicts that have resulted with state regulatory activity).

77. Meat Inspection Act of 1906, ch. 2907, titles I-IV, 34 Stat. 1260 (codified as amended at 21 U.S.C. §§ 601-695 (2000)). The passage of this law followed revelations of unsafe and unsanitary practices in the meat packing industry published two years earlier in a widely read expose. *See* UPTON SINCLAIR, THE JUNGLE, 35-47 (Pocket Books 2004) (1906) (highlighting unsanitary conditions in the meatpacking industry at the turn of the twentieth century).

78. Pure Food and Drug Act of 1906, 21 U.S.C. §§ 1-15.

79. Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-397.

80. *Id.* § 331.

81. *See* 21 C.F.R. §§ 300.50-300.100 (2007) (containing FDA regulations governing the conduct of clinical trials of new drugs).

82. *Id.*

83. This change was enacted as part of the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act, Pub. L. No. 87-781, 76 Stat. 780 (1962).

navigate before a drug can actually reach patients. The initial step in the process relates not to the safety or efficacy of the product but to the intellectual property that it represents in the form of a patent.[84] An application for a patent is filed with the federal Patent and Trademark Office (PTO).[85] At the start of clinical trials, approval is needed from an Institutional Review Board (IRB) concerning the protection of human subjects.[86] These bodies function according to federal rules but are organized by the private institutions that sponsor the research and are composed of private individuals. After the FDA approves a drug, it is subject to continuing post-market safety surveillance by the agency and ongoing review of advertising and promotional materials.[87] In order to actually reach patients, the product must be prescribed by physicians and other practitioners who are subject to the regulatory web described above, and it must be dispensed by state-licensed pharmacists.[88] Successful marketing may also depend on placement of the drug on the formularies of private prescription drug managers (PBMs) and health maintenance organizations (HMOs), which administer financing mechanisms through which patients obtain them.[89]

Other areas of regulatory concern in which the federal government takes the lead tend to be less focused than drug safety. While antitrust enforcement is effectuated at both the state and federal levels, two federal agencies represent the most active authorities in this regard: the Department of Justice and the Federal Trade Commission.[90] Antitrust law applies to all private commercial activity, but

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84. FIELD, *supra* note 2, at 119; *see also* Dennis S. Fernandez, James Huie, & Justin Hsu, *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 965-70 (Anatole Krattiger et al. eds., 2007), *available at* http://www.iphandbook.org/handbook/chPDFs/ch10/ipHandbook-Ch%2010%2009%20Fernandez-Huie-Hsu%20Patent%20and%20FDA%20Interface%20rev.pdf (discussing the PTO and FDA approval processes).

85. FIELD, *supra* note 2, at 119; *see also* MARK MATHIEU, NEW DRUG DEVELOPMENT: A REGULATORY OVERVIEW 1-14 (5th ed. 2000) (presenting background on the drug approval process); Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RESEARCH POL'Y 531, 532-36 (2000) (discussing policy changes regarding the process of obtaining a patent that occurred in the late-twentieth century).

86. MATHIEU, *supra* note 85, at 178; *see also* U.S. Dep't of Health and Human Servs., HHS Fact Sheet, Protecting Human Research Subjects (2000), http://www.hhs.gov/news/press/2000pres/20000606a.html [hereinafter HHS Fact Sheet] (discussing the role of various administrative agencies in protecting human research subjects).

87. *See* 21 C.F.R. § 314.80 (2007) (containing FDA regulations regarding post-market safety review of drugs).

88. *See* Virginie Annelaure Schubert, XRM: Integrated Customer Relationship Management for Pharmaceutical Innovation 123-26 (2005) (University of Berlin), *available at* http://edocs.tu-berlin.de/diss/2005/schubert_virginie.pdf (discussing the relationship between patient, physician, and pharmaceutical company); *see also* FIELD, *supra* note 2, at 137 (discussing state oversight of prescribing).

89. Schubert, *supra* note 88; *see also* FIELD, *supra* note 2, at 94 (discussing the regulatory roles of PBMs and HMOs).

90. U.S. Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care*, 4 Trade Reg. Rep. (CCH) ¶ 13,153 (Aug. 18, 1996) (revising its 1993 and 1994 statements on antitrust enforcement).

these agencies have directed a substantial amount of attention to health care and have issued guidelines that specifically apply to health care.[91]

The federal government has taken the lead in regulating the dissemination of patient medical information. Under HIPAA, federal rules govern the circumstances under which data may be shared by a health care provider with parties outside of the clinical relationship.[92] They also protect the ability of patients to access their own information.[93] Additional regulations impose standards on the format of patient data that is transmitted in electronic form for claims payment.[94] While HIPAA preempts most state laws that address the same issues, it permits state rules that are more stringent than federal standards to remain in force.[95]

A final example of federal primacy in health care regulation is the oversight of research involving human subjects by IRBs. Congress directed that rules be promulgated to protect participants in clinical investigations that are funded by the NIH and that form part of a manufacturer's application for approval of a new drug by the FDA.[96] Regulations in this area are issued exclusively at the federal level, although they rely on IRBs as a private enforcement mechanism.

Federal programs that directly regulate health care represent a relatively small portion of federal involvement in oversight of the industry. An additional set of programs provide funding for various kinds of health care activities subject to restrictions on its use. These programs are considered below as a separate paradigm.

C. Paradigm 3: Federal Funding with Regulatory Restrictions

An array of federal programs injects over a trillion dollars into the health care system every year.[97] In each case, the funding that is provided is accompanied by rules that encourage private actions to effectuate specific kinds of outcomes.[98] The cumulative result of these programs is a force that has been instrumental in shaping the American health care system, and they represent a distinctly American form of partnership between the government and the private sector.

The underlying premise of federal funding programs is to facilitate private activity that achieves overarching government policy. In each case, Congress has identified an area of health care in need of expansion. In response, a large sum of money has been appropriated that is distributed to private parties that actually

91. The guidelines concerning antirust enforcement in health care are known as "safety zones." They describe joint enterprises of health care providers that will not be subject to prosecution. *Id.*

92. Federal Privacy Rule, 45 C.F.R. pt. 164 (2007).

93. *Id.*

94. 45 C.F.R. § 61.13 (2007).

95. 45 C.F.R. § 160.203 (2007).

96. *See* 42 U.S.C. §§ 201, 218 (requiring IRB review of research involving human subjects as part of the National Research Act of 1974); 45 C.F.R § 46 (containing NIH regulations regarding IRBs); 21 C.F.R. § 56 (containing FDA regulations of research involving human subjects).

97. *See* Arthur Birmingham LaFrance, *Healthcare Reform in the United States: The Role of the States*, 6 SEATTLE J. FOR SOC. JUST. 199, 199 (2007) ("Total national healthcare expenditures exceed $1 trillion annually and, at the present rate of increase, will surpass $2 trillion within the present decade.")

98. *See, e.g.*, 42 C.F.R. § 493.649 (containing rules for reimbursement of private contractors that provide various kinds of services related to Medicare and Medicaid).

conduct the activities Congress has found lacking but subject to regulatory restrictions that guide the shape those activities take. These programs have addressed such key areas as hospital construction,[99] hospital operations,[100] employer-based health insurance,[101] and biomedical research.[102]

The enactment of programs that follow this paradigm reached its peak in the decades following World War II. The Hill-Burton Act funded private hospital construction and expansion throughout the country for thirty years after its enactment in 1946.[103] In order to use these funds, institutions were required to abide by a set of directives concerning their operations, including a provision requiring a substantial amount of care to indigent persons and equal treatment of patients regardless of race.[104] The law also implemented a process of health planning at the state level to guide the allocation of funding, which eventually grew into certificate-of-need programs that determined the overall distribution of health care services in each state.[105]

The federal government further shaped the hospital industry through a tax subsidy for institutions that operate on a nonprofit basis.[106] Historically, the preponderance of American hospitals has been structured in this way, and the majority, sixty-two percent, still is.[107] Through the tax subsidy, hospitals are exempted from a range of federal taxes. In addition, private individuals receive tax deductions for donations to the institutions, and bondholders avoid taxes on interest

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99. *See* Rand E. Rosenblatt, *The Four Ages of Health Law*, 14 HEALTH MATRIX 155, 168 (noting that the Hill-Burton Act "provided over four billion dollars in public funds for construction of public and private non-profit hospitals between 1946 and 1972").

100. *Id.*

101. *See* Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 YALE J. ON REG. 455, 478 ("Employer-based health insurance receives a substantial tax subsidy through both its deductibility to the employer and the failure of the Internal Revenue Code to count health insurance benefits as income to the employee.").

102. *See* Joseph Loscalzo, *The NIH Budget and the Future of Biomedical Research*, 356 NEW ENG. J. MED. 1665, 1666-67 (2006) (describing the impact of government funding on biomedical research).

103. *See* Hospital Survey and Construction Act of 1946, 42 U.S.C. §§ 291 to 291o-1 (providing billions of dollars of federal funding to construct and operate hospitals over a thirty year span); *see also* Rosenblatt, *supra* note 99, at 168.

104. *Id.*

105. Under state certificate-of-need programs, geographic regions are defined and a comprehensive plan that assesses health care needs is developed for each one. When a provider wishes to construct or expand a facility or add a new service, it must demonstrate that there is a need under the plan for its region. Only upon such a demonstration will the state grant a certificate-of-need, which the provider must obtain before committing funds for the project. States differ in the types of projects and the types of providers to which the requirement extends.

106. *See* Alice A. Noble, Andrew L. Hyams, & Nancy M. Kane, *Charitable Hospital Accountability: A Review and Analysis of Legal and Policy Initiatives*, 26 J.L. MED. & ETHICS 116, 118-19 (1998) (describing federal tax subsidies).

107. U.S. GOV'T ACCOUNTABILITY OFFICE, NONPROFIT, FOR-PROFIT, AND GOVERNMENT HOSPITALS: UNCOMPENSATED CARE AND OTHER COMMUNITY BENEFITS 4 (2006) (statement of David M. Walker, Comptroller General of the United States, before the House Committee on Ways and Means).

that they receive on hospital debt.[108] The total amount of lost revenue to the federal government is estimated at over $4 billion a year.[109] In return, hospitals must submit to rules concerning nondiscrimination, indigent care, and financial dealings with their own physicians.[110] The effect has been to encourage the provision of charitable care, community outreach, and other charitable activities as common practices among American hospitals.[111]

The operational premise behind these two programs is that while government action should address social needs, the actual activities that fill the need are best conducted at the private level. The Hill-Burton Act was intended to enhance geographical access to hospital services in underserved areas, and the tax subsidy encourages access within each community.[112] Rather than providing for direct government provision of such services, these programs allocate funding to private nonprofit organizations that take on this role.[113] In effect, the programs create a partnership in which the government provides the resources and direction and private entities provide the implementation and day-to-day operational decision making.

A second tax subsidy has nurtured and shaped the system of private employer-based health insurance that provides the largest single source of coverage in the United States.[114] The premiums paid for these policies represent a form of financial support for employees by employers, yet this support is not considered as income for purposes of federal taxation.[115] It is also exempt from state income taxes.[116] The result is an estimated total of over $209 billion a year in lost revenue for federal and state governments.[117] This money is, in effect, transferred to workers by the government as a subsidy for the purchase of coverage.

The insurance that workers buy with the help of the tax subsidy is provided by private companies. The subsidy thereby serves as a conduit through which the government adds hundreds of billions of dollars each year to the market for coverage. By subsidizing health insurance premiums, government policy has, in effect, nurtured a private insurance market and channeled it into coverage that is obtained through employment.

The largest infusion of government funding into the health care system is through the Medicare and Medicaid programs. Medicare, which provides health

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108. Internal Revenue Code, 26 U.S.C. § 501(c)(3); *see also* I.R.S. Rev. Rul. 69-545, 1969-2 C.B. 117 (concerning the tax-exempt status of hospitals).

109. CONG. BUDGET OFFICE, NONPROFIT HOSPITALS AND TAX ARBITRAGE 4 (2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7696/12-06-HospitalTax.pdf.

110. I.R.S. Rev. Rul. 69-545, 1969-2 C.B. 117.

111. *See* Noble, Hyams, & Kane, *supra* note 106, at 118-19.

112. Hospital Survey and Construction Act of 1946 (Hill-Burton Act), 42 U.S.C. §§ 291-291o-1 (2000 & Supp. IV).

113. *Id.*

114. John Sheils & Randall Haught, *The Cost of Tax-Exempt Health Benefits in 2004*, HEALTH AFFAIRS (WEB EXCLUSIVE), Feb. 25, 2004, at W-4 111, http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.106v1.pdf.

115. *Id.* at 106.

116. *Id.* at 108.

117. *Id.*

insurance for the elderly and disabled, spends over $330 billion a year on the purchase of health care services, and Medicaid, which covers several categories of the very poor, over $289 billion.[118] Medicare, in particular, exerts a tremendous regulatory influence, as it represents a large portion of the revenue of many hospitals and physicians. Attached to this funding are numerous restrictions. Hospitals and physicians must meet conditions of participation that screen for quality-related factors.[119] By paying hospitals through a prospective system based on patient diagnosis, Medicare has encouraged efficiency in many medical procedures and the movement of large amounts of care to outpatient settings.[120] The Emergency Medical Treatment and Active Labor Act,[121] which requires open access to emergency rooms as a condition of Medicare participation, has opened the use of these facilities to many indigent patients. Decisions as to what procedures and devices Medicare will cover are often followed by private insurers, making Medicare a leading force in determining the kinds of clinical care that are available in the United States.

In no aspect of health care is the public-private regulatory paradigm clearer than in the funding of biomedical research. NIH is unique in the world. No other country spends as much on research, and in none is the role of private investigators as central.[122] The federal government devotes about $28 billion a year to NIH-funded studies.[123] Of this amount, about eighty percent supports research in private institutions.[124] These investigations are initiated by the researchers themselves, who submit proposals for funding that are reviewed by their professional peers who work at other private institutions.[125] Through the peer review process, the research questions and methodologies are developed and approved by people outside of the government. The primary role of government policy is to set general research directions through budget allocations, which determine spending in various fields

118. U.S. Dep't of Health and Human Servs., FY 2005 Budget in Brief: Centers for Medicare & Medicaid Services, http://www.hhs.gov/budget/05budget/centersformed.html (last visited Apr. 15, 2008) (listing the Medicare budget for the fiscal year 2005 as $331,261,000, and the total budget for Medicaid for fiscal year 2005, including both the shares paid by the federal and states governments, as $289,100,000).

119. *See* Ctrs. for Medicare and Medicaid Servs., Survey & Certification – Guidance to Laws & Regulations: Overview, http://www.cms.hhs.gov/CFCsAndCoPs/01_Overview.asp (last visited Apr. 15, 2008) (discussing the conditions of participation for providers in Medicare).

120. *See* Sakesun Suthummanon & Vincent K. Omachonu, *DRG-Based Cost Minimization Models: Applications in a Hospital Environment*, 7 HEALTH CARE MGMT. SCI. 197, 203 (2004) (utilizing a cost-minimization analysis, results show that based on a little over 6000 admissions for selected DRG's in 2000, the total cost per year decreased by 11.58% and the total cost per patient per day decreased by 10.35%).

121. 42 U.S.C. § 1395dd.

122. HARDEN, *supra* note 30.

123. NAT'L INSTS. OF HEALTH, NATIONAL INSTITUTES OF HEALTH HISTORY OF CONGRESSIONAL BUDGET APPROPRIATIONS, 2000-2006 (2006), *available at* http://officeofbudget.od.nih.gov/UI/..%5CPDF%5Cappic%202000%20-%202006.pdf (listing the NIH budget in fiscal year 2006 as $28,461,417).

124. Nat'l Insts. of Health, About NIH, http://www.nih.gov/about/NIHoverview.html (last visited Apr. 15, 2008).

125. *Id.*

of study.[126] This collaboration between government and private researchers has produced monumental strides in the advance of medicine and has contributed to discoveries resulting in over 100 Nobel prizes.[127]

When considered as a whole, the government programs that reflect the third paradigm have transformed American health care and effectively created the structure that exists today. A few examples illustrate how pervasive that influence has been. The hospital industry would be a fraction of its present size if not for the Hill-Burton and Medicare programs. There would not only be fewer hospitals, particularly in rural areas, but hospitals would also be smaller. Without Medicare, much of the medical profession would likely see significantly lower incomes, and there would be fewer incentives for new physicians to enter specialties that focus on geriatric patients. The private insurance industry would be unable to cover as many people without the tax subsidy, and a smaller percentage of coverage would be offered through employers. Without the infusion of billions of NIH dollars into basic biomedical research, it would be difficult for private pharmaceutical companies to conduct the large amount of applied research that has led to the industry's tremendous growth over the past several decades.[128]

V. IMPLICATIONS FOR HEALTH REFORM

Regulatory changes that are needed to effectuate health reform can proceed under each of these paradigms. Various proposals have relied on different ones or on a combination of them. The structure of existing programs that fall under each paradigm may offer guidance as to the elements that will determine the success of future reform efforts.

A. *Reform Under State Primacy*

The programs that fall within the state primacy paradigm are embedded in broader webs of regulatory authority. While the states take the lead, they represent only one group of players on a larger stage. Therefore, to fit within this paradigm, any meaningful reform would have to orchestrate the inclusion of a range of other agencies and organizations beyond state jurisdiction.

The kinds of reforms over which states have jurisdiction are somewhat limited. Proposals that have been enacted or which have engendered serious

126. *See* James B. Wyngaarden, *The National Institutes of Health in Its Centennial Year*, 237 SCIENCE 869, 869-74 (1987) (describing the political dimensions of developing and allocating the yearly NIH budget).

127. Nat'l Insts. of Health, *supra* note 124.

128. *See* Hamilton Moses, E. Ray Dorsey, David H. M. Matheson, & Samuel O. Thier, *Financial Anatomy of Biomedical Research*, 294 J. AM. MED. ASS'N, 1333, 1333-41 (2005) (discussing the financing of industry-sponsored research in the development of new pharmaceutical products); *see also* Robert I. Field, Barbara J. Plager, Rebecca A. Baranowski, Mary Anne Healy, & Margaret L. Longacre, *Toward a Policy Agency on Medical Research Funding: Results of a Symposium*, HEALTH AFF., May/June 2003, at 224-30 (discussing the role of industry-sponsored research in the development of new pharmaceutical products).

legislative discussion have included three primary elements.[129] First, they alter the regulatory structure of insurance to encourage the sale of policies directly to individuals rather than through employers.[130] This generally takes the form of limitations on the ability of insurers to underwrite individual policies for medical reasons in order to improve access to insurance for those who are unemployed, self-employed, or whose employers do not offer coverage.[131] Second, they provide subsidies for those with low incomes who seek to purchase individual policies.[132] Finally, and most significantly, some state reform proposals include mandates that coverage be provided by employers, obtained by individuals, or some combination of the two.[133]

To succeed, these state-level measures must achieve consistency with a range of external regulatory dictates. Most importantly, they must avoid preemption by ERISA.[134] However, courts have not generally looked favorably on state reform efforts in this context.[135] For example, Maryland's attempt to mandate coverage of workers by the state's largest employers was invalidated based on ERISA preemption.[136] State insurance reforms would also have to be consistent with the provisions of COBRA and HIPAA concerning continuation of coverage.[137] In addition, any state program would have to be coordinated across jurisdictions with regard to residents who move, have dependents living in other states, or work for out-of-state firms. Such coordination is typically handled for state programs by a federal authority, for example, the NPDB, which coordinates physician licensure activities. Isolated state programs can leave gaps that threaten their effectiveness.

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129. These elements are contained in the health reform plan that was implemented in Massachusetts in 2007 and in one that has been proposed for California. *See* John E. McDonough, Brian Rosman, Fawn Phelps, & Melissa Shannon, Web Exclusive, *The Third Wave of Massachusetts Health Care Access Reform*, HEALTH AFF. at W420, W420-31 (Nov./Dec. 2006), http://content.healthaffairs.org/cgi/reprint/25/6/w420 [hereinafter *Third Wave*] (discussing the components of and implementation issues in the Massachusetts health care reform plan enacted in 2006); *see also Governor's Health Care Proposal* (2007), http://gov.ca.gov/pdf/press/Governors_HC_Proposal.pdf (outlining the California proposal).

130. *See, e.g.*, AM. MED. ASS'N HEALTH POLICY GROUP, EXPANDING HEALTH INSURANCE: THE AMA PROPOSAL FOR REFORM 5 (2007), http://www.ama-assn.org/ama1/pub/upload/mm/363/ehi1012.pdf [hereinafter EXPANDING HEALTH INSURANCE].

131. *Id.* at 9.

132. *Id.* at 6.

133. *See Third Wave*, *supra* note 129, at W420-31.

134. William Pierron & Paul Fronstin, Employee Benefit Research Inst., *ERISA Pre-emption: Implications for Health Reform and Coverage*, ISSUE BRIEF, Feb. 2008, at 1, 12, *available at* http://www.ebri.org/pdf/briefspdf/EBRI_IB_02a-20082.pdf; *see also* PATRICIA A. BUTLER, NAT'L ACAD. FOR STATE HEALTH POLICY, ERISA PREEMPTION MANUAL FOR STATE HEALTH POLICYMAKERS 18-19 (2000), *available at* http://statecoverage.net/pdf/erisa2000.pdf (discussing the scope of ERISA and how the Act affects state health policy).

135. *See, e.g.*, Retail Indus. Leaders Ass'n v. Fielder, 475 F.3d 180, 197 (4th Cir. 2007) (holding that Maryland's Fair Share Health Care Fund Act was preempted by ERISA).

136. *Id.*

137. Comprehensive Omnibus Budget Reconciliation Act of 1986, 29 C.F.R. §§ 2590.606-1 to 2590.736 (2008); Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. § 164.508(b)(4) (2008). These regulations were promulgated pursuant to COBRA, 29 U.S.C. §§ 1161-1169, and HIPAA, 42 U.S.C. §§ 300gg to 300gg-92.

B. Reform Under Federal Primacy

Regulatory reform at the federal level is the most direct way to reshape the health care system. Federal reform is the primary means through which incremental reform has been accomplished in the past. Notable among such measures have been the Health Maintenance Organization Act of 1973,[138] which facilitated the spread of managed care, and ERISA. More recent federal regulatory reforms have included the insurance continuation provisions of COBRA and HIPAA and the underwriting restrictions contained in HIPAA.[139]

Further federal reforms could reshape the private insurance market.[140] They could, for example, encourage growth in the market for individual policies. Possible steps in this direction would be to change the tax-favored status of employer-provided coverage, to further restrict the medical underwriting practices of insurers for chronic conditions, and to facilitate pooling of risks across state lines. Federal reforms could also mandate that employers obtain coverage for their workers or that individuals acquire insurance for themselves and their dependents. To effectively change the insurance market and substantially increase access to coverage, a federal regulatory effort would have to preempt a significant amount of the authority that states presently have to oversee the business of insurance as it applies to health care.

The clearest existing model for federal primacy in health care regulation is the oversight of drugs. As with the programs that fall under state primacy, drug regulation includes a significant role for private players, who comprise the IRBs that supervise the protection of human subjects in clinical trials and the FDA advisory committees that advise the agency on many new drug applications.[141] If federal health insurance regulation were to succeed at achieving more than incremental change under to this model, coordination between governmental and private authorities would be needed. The result would be a complex new bureaucratic structure.

Health reform that relies on federal primacy holds the appeal of producing the most direct national effect. It avoids the need for coordination across jurisdictions that state primacy requires. However, it raises its own set of challenges and grounds for political resistance, as it would change the existing business model of private insurance without injecting substantial new funding into the system. As a result, its promise lies primarily in further incremental, rather than wholesale change.

C. Reform Under Federal Funding with Regulatory Restrictions

The regulatory paradigm that is most likely to effectuate significant reform is the use of federal funding with regulatory restrictions. This approach has

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138. 42 U.S.C. §§ 280(c), 300(c).

139. *Supra* note 137 and accompanying text.

140. *See, e.g.*, EXPANDING HEALTH INSURANCE, *supra* note 130, at 1 (outlining the American Medical Association proposal for health care reform).

141. *See* HHS Fact Sheet, *supra* note 86 (discussing the role of various administrative agencies in protecting human research subjects).

historically been the most influential in expanding health care access. Medicare, Medicaid, and the tax subsidy for employer-sponsored plans shape the coverage of the vast majority of Americans who have health insurance. All of these programs channel substantial amounts of money into the health care system and orchestrate collaborations between large numbers of different players.

Health reform according to this paradigm could expand Medicare, Medicare, or the State Children's Health Insurance Program (SCHIP). Proposals along these lines have called for steps such as lowering the age of eligibility for Medicare, raising the income limit for participation in Medicaid, and permitting parents of eligible children to participate in SCHIP.[142] More dramatic reforms would create a single federal insurance program to provide coverage for all citizens.[143] A more modest use of this paradigm would extend tax deductions or tax credits for the purchase of individual health insurance policies.[144]

All of these approaches to health reform would be extremely costly. The lowest estimates for a system that would cover all of those who are presently uninsured are in the range of $34 to $69 billion a year.[145] Ambitious plans could cost over $100 billion.[146] They would also all rely on a complex partnership between the public and private sectors. Medicare uses private insurance companies to administer claims as carriers under Part A and intermediaries under Part B.[147] Medicaid in all states is provided to a substantial extent through private managed care organizations, as is much of the coverage under SCHIP.[148] An enhanced tax

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142. JUDITH FEDER, CORI UCCELLO, & ELLEN O'BRIEN, KAISER FAMILY FOUND., THE DIFFERENCE DIFFERENT APPROACHES MAKE: COMPARING PROPOSALS TO EXPAND HEALTH INSURANCE 21-26 (1999), *available at* http://www.kff.org/uninsured/upload/The-Difference-Different-Approaches-Make-Comparing-Proposals-to-Expand-Health-Insurance-Report.pdf (describing different approaches to incremental health care reform); INST. OF MED., INSURING AMERICA'S HEALTH: PRINCIPLES AND RECOMMENDATIONS 4-5 (2004) (offering a checklist of five principles useful in assessing coverage proposals and their implicit tradeoffs).

143. A proposal for a single-payer universal health care plan has been developed by The Physicians' Working Group For Single-Payer National Health Insurance, an association of physicians, medical students, and health professionals. The Physicians' Working Group for Single-Payer Nat'l Health Ins., *Proposal of the Physicians' Working Group for Single-Payer National Health Insurance*, 290 J. AM. MED. ASS'N, 798, 805 (2003).

144. FEDER, UCCELLO, & O'BRIEN, *supra* note 142 at 5.

145. INST. OF MED., HIDDEN COSTS, VALUE LOST: UNINSURANCE IN AMERICA 103 (2002); *see also* FEDER, UCCELLO, & O'BRIEN, *supra* note 142, 26-28 (estimating the costs of various incremental health reform proposals).

146. The plan proposed by Senator Hillary Clinton of New York in 2007 to provide universal coverage is estimated to cost $110 billion a year. HILLARY CLINTON, THE AMERICAN HEALTH CHOICES PLAN: ENSURING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS 13 (2007), *available at* http://www.hillaryclinton.com/feature/healthcareplan/americanhealthchoicesplan.pdf.

147. *See* Susan Bartlett Foote, *Focus on Locus: Evolution of Medicare's Local Coverage Policy*, HEALTH AFF., July/Aug. 2003, at 137, 137-45 (describing Medicare's use of private insurance companies to administer claims).

148. *See* John Holahan, Stephen Zuckerman, Alison Evans, & Sureh Rangarajan, *Medicaid Managed Care in Thirteen States*, HEALTH AFF., May/June 1998, at 43, 43-61 [hereinafter *Medicaid Managed Care*] (discussing the use of private managed care companies to deliver Medicaid services); Marsha Gold, Jessica Mittler, Debra Draper, & David Rousseau, *Participation of Plans and Providers in Medicaid and SCHIP Managed Care*, HEALTH AFF., Jan./Feb. 2003, at 230, 233-34 (discussing the use of managed care to provide benefits under Medicaid and under SCHIP).

subsidy for individuals would rely on existing private insurance companies to continue to provide coverage. A single payer system has not yet been implemented, but it is likely that private sector participation would be necessary, as well, for any program to succeed.

Programs such as these are the most likely to achieve significant, rather than incremental expansion of access to health insurance. They represent the most direct approach and provide clear sources of funding. A substantial health reform plan under this paradigm could have the transformative effect on American health care that other kinds of funding programs have had in the past. Over the long run, private health care providers could see tremendous opportunities to flourish as funds are channeled to patients to improve their access to care. Even private insurers might discover new markets under such programs.

However, because they are the most transformative, federal funding programs are likely to engender the most intense political opposition. For example, private insurers may see their traditional model of operations threatened.[149] Medical specialists could see new layers of utilization review. Pharmaceutical companies could see new patient incentives to use generic drugs. The plan proposed by President Bill Clinton faced such opposition in 1994 and eventually succumbed.[150] Objections could also arise based on opposition to new federal expenditures and to an expansion of the government's role in health care.[151] For these reasons, health care reform along the lines of past government programs such as the Hill-Burton Act, Medicare, and NIH are the least likely to achieve the political consensus needed for enactment.

VI. THE FUTURE OF HEALTH REFORM AND THE ROLE OF THE STATES

The history of efforts to achieve health reform reflects the perennial difficulty of this endeavor. President Franklin Roosevelt hoped to achieve universal health coverage as part of the New Deal in the 1930s, much as Social Security provided a form of universal pension protection.[152] He had to put his plan aside because of political opposition and the start of World War II. President Harry Truman continued the effort in the 1940s but had to settle for the Hill-Burton Act as a means of expanding health care access. President Lyndon Johnson spearheaded the enactment of Medicare and Medicaid in the 1960s as a first step toward universal coverage, but the next steps have yet to take place. President Bill Clinton thought

149. *Medicaid Managed Care*, *supra* note 148, at 53.

150. *See* THEDA SKOCPOL, BOOMERANG: CLINTON'S HEALTH SECURITY EFFORT AND THE TURN AGAINST GOVERNMENT IN U.S. POLITICS, 6-19 (1996) (describing the downfall of the Clinton Health Security bill and noting that socially inclusive health reforms remain doubtful for the future); Robert J. Blendon, Mollyann Brodie & John Benson, *What Happened to Americans' Support for the Clinton Health Plan*, HEALTH AFF., Summer 1995, at 7, 9 (discussing how a series of key strategic and substantive misjudgments in the development of the plan caused a decrease in public support).

151. Blendon, Brodie & Benson, *supra* note 150, at 10.

152. *See* STARR, *supra* note 20, at 363-78 (describing the history of political efforts to enact national health insurance in the United States and of the creation of Medicare and Medicaid).

that the time for those steps had arrived in the 1990s but discovered that political conditions still dictated otherwise.[153]

Efforts to reform health care at the state level have sought to fill the gap left by the repeated failures of federal initiatives. They have seen legislative success in a small handful of states, most notably Massachusetts.[154] However, it is still too early to assess the outcome of implementation of these programs.[155] To make a meaningful change in access to health care, state programs will face a considerable challenge in achieving coordination across jurisdictions and in devising collaborative relationships with private regulatory organizations. These results will be difficult to achieve without federal involvement.

Efforts to enact reform through federal regulation would be more direct and easier to implement nationally. They would obviate the need for coordination across states and could directly overrule existing laws, such as ERISA, that may impede state initiatives. However, without a significant commitment of new funding, they are likely to be incremental in nature.

Reform according to the paradigm of federal funding with regulatory restrictions would follow the model that past champions of universal coverage have sought to achieve. It would proceed along the lines of Medicare, Medicaid, SCHIP, and the tax subsidy for employer-sponsored coverage. However, because of its threat to many existing health care business arrangements, which have grown more complex over time, such efforts actually seem to face political resistance that grows stronger with each successive attempt.

As the most politically feasible approach, state level health reform may find increasing acceptance. While each individual state will encounter challenges of its own, a collection of states with reform programs could begin to build political momentum. With coordinated efforts to promote state-by-state reform, programs could begin to spread nationally much as medical licensure did at the end of the nineteenth century. With enough states involved, difficulties in coordination would likely become increasingly apparent. This could provide proponents with an opportunity to advocate for an enhanced federal role. In this way, state primacy could provide a foundation for the political consensus needed to achieve national changes. Were this process to proceed, states could serve as laboratories for the politics of health reform, even as they grapple with its actual implementation.

CONCLUSION

Health care will perennially command political attention. It directly affects the lives and well being of every citizen and, in accounting for sixteen percent of the gross domestic product, drives much of the American economy.[156]

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153. Blendon, Brodie & Benson, *supra* note 150, at 19-21.

154. *See* Robert Steinbrook, *Health Care Reform in Massachusetts—A Work in Progress,* 354 NEW ENG. J. MED. 2095, 2097 (2006), *available at* http://content.nejm.org/cgi/reprint/354/20/2095.pdf (describing health care reforms in Massachusetts).

155. *Id.*

156. U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL HEALTH EXPENDITURE ACCOUNTS: 2006 HIGHLIGHTS 1 (2006), http://www.cms.hhs.gov/NationalHealthExpendData/downloads/ highlights.pdf.

Imperfections in the system will always engender political discussion, and no imperfection is as glaring as the lack of financial access for 46.5 million citizens.[157] Because of the breadth of the health care industry and the intricacy of its scientific base, the regulation of health care forms a complex web comprised of authorities at every level of government and in the private sector. Reforms will have to be integrated into this web.

Within the array of regulatory programs and regulatory bodies, three basic approaches to the oversight of health care can be discerned. One is led at the state level, one is led at the federal level, and one provides federal funding subject to regulatory direction. Based on historical precedent, the final approach is the most likely to achieve meaningful change but the least likely to achieve political consensus. Recent efforts for reform at the state level are more limited in reach but have the potential to command greater political support. However, the state-level health care regulatory programs that are in effect today do not exist in isolation. Rather, they form the foci for networks of different kinds of regulatory mechanisms. Therefore, based on historical precedent, if state reforms are to survive and flourish, they will eventually have to form the structure and create the political constituency for broader national efforts.

In holding a central place in the social and economic fabric of the country, many aspects of health care follow patterns that are distinct from the rest of American business. The regulation of the industry is no exception. As a result, reform through regulatory change is unlikely to follow a conventional path of implementation through a single legislative effort. The road to health care reform is likely to be confusing, complex, and circuitous, with a resulting regulatory structure that is no different. Historical patterns of regulation can serve as a guide to the kinds of outcomes to which reform may lead.

157. KAISER COMM'N ON MEDICAID & THE UNINSURED, HENRY J. KAISER FAMILY FOUND., KEY FACTS: THE UNINSURED AND THEIR ACCESS TO HEALTH CARE (Oct. 2007), *available at* http://www.kff.org/uninsured/upload/ 1420_09.pdf.