

THE FIRST FIFTY YEARS: HEALTH LAW'S GREATEST HIT

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INTRODUCTION

The law review editor's suggestion was inviting: "How about an essay on the most important development in your field in the last fifty years?"

This sounded pretty easy,¹ at first. It should have been obvious to

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1. It sounded easy in part because a 50-year review in the field of Health Law would involve only about 30 years' worth of developments in this young area of legal specialization. One of the first signs that health law had established a professional identity for itself was the creation of professional associations for health lawyers. The American Academy of Hospital Attorneys was created in 1968 "as a personal membership group of the American Hospital Association to serve the needs of attorneys representing hospitals and

me—someone who freezes whenever he is asked to name his favorite poet,² Motown hit,³ or dessert⁴—that this assignment might be a lot of things, but “easy” wouldn’t be one of them.

Part of the difficulty stems from the diverse nature of the field of “health law” itself. For example, I might have chosen the modern judicial restatement of the law of informed consent,⁵ the first “right to die” case,⁶

health systems,” followed by the founding of the National Health Lawyers Association in 1971. See American Health Lawyers Ass’n, *History: About Health Lawyers* (updated Aug. 22, 2000) <http://www.healthlawyers.org/about_history.htm>. The two organizations merged in 1997 to form a 10,000-member organization that eventually became known as the American Health Lawyers Association . *Id.*

Health law courses were presumably being taught in American law schools in the late 1970s and 1980s, but the phrase “Health Law” did not see its way into a casebook title until 1987. See BARRY R. FURROW, SANDRA H. JOHNSON, TIMOTHY S. JOST & ROBERT L. SCHWARTZ, *HEALTH LAW: CASES, MATERIAL & PROBLEMS* (1987). The casebook that had previously defined the field of Law & Medicine for a generation was LAW, MEDICINE & FORENSIC SCIENCE by one of the pioneers in this field, Professor William J. Curran (joined later by Professor E. Donald Shapiro). The third edition (published in 1982) retained the book’s focus on medical liability issues, although it included “cursory sections on reimbursement issues and health planning,” Clifford D. Stromberg, *Health Law Comes of Age: Economics and Ethics in a Changing Industry*, 92 YALE L.J. 203, 217 (1982), a brief section on antitrust, *id.* at 214, and a single chapter on regulation in the health care industry, *id.* at 209. After the addition of Professor Mark Hall as a co-editor on the fourth edition, the Curran casebook moved even more strongly toward coverage of health-law topics. The transformation of the Curran casebook into a health-law text is now complete. See WILLIAM J. CURRAN, MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, *HEALTH CARE LAW & ETHICS* (5th ed. 1998).

2. Another attractive feature of this assignment was that the editors asked for an “essay,” not an “article.” In the parlance of the trade, this means the piece could be shorter than a “real” law review article; could be more casually documented; could include contractions and other, y’know, verbal tics; and could eschew lengthy textual footnotes (*but see supra* note 1). So if you’re reading this footnote because you were expecting a copiously researched and learned discussion of the history of poetry in the English language from the 12th through the 20th centuries, *see instead* MICHAEL SCHMIDT, *LIVES OF THE POETS* (1999).

3. *Cf. supra* note 2. See also SUZANNE E. SMITH, *DANCING IN THE STREET: MOTOWN AND THE CULTURAL POLITICS OF DETROIT* (2000); *EVERY GREAT MOTOWN SONG: VOL. 1, 1960s* (Motown Records 1988), *VOL. 2, 1970s* (Motown Records 1989).

4. *Cf. supra* note 3. See also HOUSTON JUNIOR LEAGUE COOKBOOK 372 (1992) (recipe for *creme brûlée*).

5. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). Judge Spottswood Robinson’s scholarly opinion is the intellectual forerunner of the patients’ rights movement and appears in nearly every health law casebook and most first-year torts casebooks, as well. I could list the titles of all those books, of course, *but cf. supra* note 2.

6. In *re Quinlan*, 355 A.2d 647 (N.J.), *cert. denied*, 429 U.S. 922 (1976). The implications of the “right to die” movement, which arguably received its greatest boost from the *Quinlan* case, are still being worked out in the arena of physician-assisted suicide, which has generated one state statute that legalizes the practice, *see* OR. REV. STAT. §§ 127.800-.897 (1997) (Oregon Death With Dignity Act); significant litigation in the United

the decision by the Internal Revenue Service to water down its "charity-care" requirement for hospitals that seek tax-exempt status,⁷ the extension of the federal antitrust laws to the "learned professions"⁸ (including physicians), or even the enactment of the Employee Retirement Income Security Act of 1974.⁹ Each of these developments could be said to have profoundly changed the law and also to have altered the cultural landscape of health care beyond the sphere in which those events occurred. At the

States Supreme Court, *see* *Vacco v. Quill*, 521 U.S. 793 (1997), and *Washington v. Glucksberg*, 521 U.S. 702 (1997); and a nasty fight among Congress, the Clinton Administration's Justice Department, and (*in absentia*) the state of Oregon, *see* Pain Relief Promotion Act of 1999, H.R. 2260, 106th Cong., and Sam Howe Verhovek, *Oregon Chafes at Measure to Stop Assisted Suicides*, N.Y. TIMES, Oct. 29, 1999, at A1. One version of the Pain Relief Promotion Act of 1999 passed the House on October 27, 1999, 145 Cong. Rec. H10,868-10,903 (daily ed. Oct. 27, 1999) (debate and roll call vote on H.R. 2260 as amended), and a quite different version was reported out of the Senate Judiciary Committee on Apr. 27, 2000, *see* Stephen Power, *Senate panel OKs anti-suicide bill*, DES MOINES REG., Apr. 28, 2000, at 4. Meanwhile, Maine has a physician-assisted suicide proposal on the November 2000 ballot. At the time this article was being prepared for publication, voters appeared evenly split over the measure. *See* Susan Young, *Latest poll gives Gore lead over Bush in Maine*, BANGOR DAILY NEWS, Oct. 26, 2000, at B1 (describing poll that showed support and opposition both at 43.5% and undecideds at 13%).

7. Rev. Rul. 69-545, 1969-2 C.B. 117. This decision dropped the requirement of charity care that was announced in Rev. Rul. 56-185, 1956-1 C.B. 202 (requiring a tax-exempt hospital to be operated "to the extent of its financial ability for those not able to pay for the services rendered"). Revenue Ruling 69-545 also spawned one of the Supreme Court's major "standing" decisions. *See* *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26 (1976) (introducing the requirements of "traceability" and "redressability").

8. *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975). Although it can be debated whether the antitrust laws have been over- or under-enforced in the health care industry, there can be little doubt that the regulatory impact of the laws in the post-*Goldfarb* era has been great. That impact is well documented in CLARK C. HAVIGHURST, JAMES F. BLUMSTEIN & TROYEN A. BRENNAN, *HEALTH CARE LAW & POLICY* 499-590 (2d ed. 1998). *See also* U.S. DEP'T OF JUSTICE & FEDERAL TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT IN HEALTH CARE (Aug. 1996), available at <<http://www.usdoj.gov/atr/public/guidelines/0000.htm>>.

9. 29 U.S.C. §§ 1001 et seq. (1994 & Supp. III). Even though ERISA isn't technically a health care law at all, its impact on health law has been profound. For example, most of the large employers in the country sponsor self-insured health care benefit plans primarily for one reason—thanks to ERISA, the benefit plans can avoid the various states' mandated-benefits laws, state insurance regulations, and liability for coverage decisions. *See* CLARK C. HAVIGHURST, JAMES F. BLUMSTEIN & TROYEN BRENNAN, *HEALTH CARE LAW & POLICY* 219-20 (2d ed. 1998), quoting Robert A. Berenson, *Beyond Competition*, HEALTH AFF. 171, 172 (March/April 1997). Of course, the law in this area is not nearly as clear-cut and settled as the previous sentences would imply. *See, e.g.,* *Pegram v. Herdrich*, 120 S. Ct. 2143 (2000) (exploring some of the complexities of such statutory terms as "plan" and "fiduciary," parsing the "practically inextricable" concepts of "treatment decision" and "eligibility decision," testing the distinction between for-profit and nonprofit HMOs, and considering (without resolving) some of the implications of ERISA preemption for state medical malpractice claims against HMOs).

same time, however, each of these developments was a “health law” development only because health law is a hybrid discipline that has absorbed large amounts of tort law, constitutional law, tax law, and antitrust law, to name just a few influences.

My choice for the single most significant development in this field has, like the examples above, profoundly changed the body of health law. And, like the other examples, it has altered the cultural landscape in which health care is delivered. But it has also changed the politics of health care, the financing of health care, and the availability and quality of health care in this country. It has all but defined a unique body of law that is readily identifiable as “health law,” as opposed to tort, antitrust, or tax law as applied to providers of health care goods and services, while at the same time producing spillover effects in many of the related areas of law that contribute to health law as a specialty. If these effects are accepted as the criteria by which my choice is to be made, I can truthfully think of only one candidate: the passage of the Medicare law in 1965.¹⁰

The Medicare program began with the modest aspiration to provide basic health insurance benefits for seniors sixty-five years of age and older, some citizens with disabilities, and persons with chronic kidney disease. Its initial funding was modest as well—a mere \$3.4 billion in fiscal year 1967,¹¹ or 2.15 percent of the \$158.3 billion federal budget.¹² The perception of the American Medical Association and others, however, was that Medicare was the first, immodest step toward the socialization of American medicine. Thus, part of the political compromise that was necessary to overcome the opposition of the American Medical Association is embodied in the first section of the Medicare law:

10. The Medicare Act, an insurance program that provides health care benefits primarily for those over 65 years of age and the disabled, and the Medicaid Act, an entitlement program that provides health care benefits for those who qualify on the basis of financial need, were both enacted in 1965. *See* Pub. L. No. 89-97, 79 Stat. 291 (1965). In certain instances, the Medicare and Medicaid programs each produced the effect described in this essay, as for example when certain conduct on the part of the provider was made a condition of participation in both programs. I have not parsed the effects of the two programs in this essay, however, because (1) my main focus is on Medicare, (2) distinguishing between the two is not very illuminating when both programs produced the same effect, and (3) it is easier to discuss the impact of Medicare alone without the added (and mostly unnecessary) burden of separating Medicare effects from Medicaid effects in the text.

11. *See* U.S. HOUSE COMMITTEE ON WAYS & MEANS, 105TH CONG., 1ST SESS., *MEDICARE & HEALTH CARE CHARTBOOK* 82 (Comm. Print 1997) (hereinafter *MEDICARE CHARTBOOK*).

12. BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE, 2 *HISTORICAL STATISTICS OF THE UNITED STATES: COLONIAL TIMES TO 1970* at 1105, Series Y 339-342 (1975) (hereinafter *HISTORICAL STATISTICS*).

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.¹³

There is probably no physician or patient in the country who believes this promise has been kept. Moreover, as the following sections show, what Medicare has wrought is nothing less than a revolution in the way health care (and along the way, health law) is experienced and understood some thirty-five years after its inception.

I. "HE WHO PAYS THE PIPER . . ."

One of the keys to understanding the impact of the Medicare program on health law is to see the impact of the program on health care expenditures. In 1995 constant dollars, the Medicare program's total outlays have gone from \$13.8 billion in fiscal year 1967¹⁴ (or 2.15 percent of total federal outlays¹⁵) to \$180.1 billion in fiscal year 1995¹⁶ (or 11.88 percent of total federal outlays¹⁷). It now ranks as the fourth largest federal program (behind only Social Security, defense, and interest on the national debt).¹⁸

The growth in Medicare expenditures tracks the overall growth in federal health spending, which in 1960 (before the enactment of the

13. 42 U.S.C. § 1395 (1994). Although proposals for government-sponsored health insurance in the 20th century date back at least to 1918, political realities made Medicare a possibility only once the Democrats captured both houses of Congress and the Presidency in 1961. See THEODORE R. MARMOR, *THE POLITICS OF MEDICARE 5-39* (1970). As proposed in 1961, Medicare would have covered hospital and nursing-home—but not surgical—expenses, a considerable watering down of previous proposals for universal health insurance. *Id.* at 39. Even a program of such modest goals had to be sold very carefully to the American public and the medical profession. President Kennedy was clear that “[t]he program is not socialized medicine. . . . It is a program of prepayment for health costs with absolute freedom of choice guaranteed. Every person will choose his own doctor and hospital.” *Id.* at 40. The importance of this guarantee four years later, when the Medicare legislation was signed into law, is reflected in § 1395.

14. See *MEDICARE CHARTBOOK*, *supra* note 11, at 86.

15. See *supra* text accompanying note 12.

16. See *MEDICARE CHARTBOOK*, *supra* note 11, at 86.

17. See BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE, 1999 STATISTICAL ABSTRACT OF THE UNITED STATES 348, Table No. 542 (2000) (hereinafter 1999 STATISTICAL ABSTRACT).

18. See Timothy Stoltzfus Jost, *Governing Medicare*, 51 ADMIN L. REV. 39, 40 (1999).

Medicare and Medicaid programs) was 3.3 percent of all federal expenditures and by 1995 had grown to 20.0 percent.¹⁹ Similarly, our total health expenditures (from all public and private sources) as a percentage of gross domestic product increased from 5.1 percent to 13.7 percent over the same period; much of that 269 percent increase was obviously fueled by the 548 percent increase in federal outlays for health care.

As has been commonly observed for a number of years,²⁰ the size of the health care economy, measured as a percentage of gross domestic product, represents the largest single sector of the national economy and exceeds defense and education combined.²¹ Fully 22 percent of the health care economy is paid with Medicare dollars.²²

One of the significant social consequences of the federal programs has been a growth in per capita spending on health care that not only exceeds other developed countries but also is increasing at a rate that has the United States pulling away from the pack.²³ Over the past thirty years, Americans have developed an increasing appetite for health care goods and services, one that has been fueled by government payment programs and satisfied by a steadily growing health care economy.

Moreover, most hospitals and many physicians are even more dependent upon Medicare revenue than these numbers would suggest. This is so because, compared to persons under the age of sixty-five, Medicare beneficiaries see their physicians more often, are hospitalized more frequently, and experience longer average lengths of stay in hospitals.²⁴ As

19. See U.S. DEP'T OF HEALTH & HUMAN SERVICES, HEALTH, UNITED STATES, 1999, at 283 (1999) (hereinafter HEALTH 1999).

20. See, e.g., PAUL STARR, THE LOGIC OF HEALTH-CARE REFORM 24 (1992).

21. For 1997 (the most year for which there are data in all relevant categories), the percentages are 3.4% for defense, see 1999 STATISTICAL ABSTRACT, *supra* note 17, at 888, Table No. 1444; 7.0% for education, see *id.* at 163, Table No. 254; and 13.5% for health, see HEALTH 1999, *supra* note 19, at 283, Table No. 115.

22. See BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY STOLZFUS JOST & ROBERT L. SCHWARTZ, HEALTH LAW 537 (2d ed. 2000).

23. Per capita spending on health care in the United States in 1960 was about twice as high as in Great Britain, nearly 40% higher than in Canada, about 55% higher than in Germany, and more than five times higher than in Japan. By 1994, the United States' spending was nearly three times higher than in Great Britain, about 75% higher than in Canada, and nearly twice that of Germany. Only Japan's level of per capita expenditures grew at a faster rate than the United States'—perhaps reflecting its low level of health care spending in 1960 and the robust performance of its economy after World War II—but our level of spending was still about 250% higher than Japan's. See MEDICARE CHARTBOOK, *supra* note 11, at 12, Table 1.6.

24. See 1999 STATISTICAL ABSTRACT, *supra* note 17, at 134, Table No. 199 (Visits to Office Based Physicians), and at 138, Table No. 207 (Hospital Utilization Rates: 1980 to 1996)).

a result, federal spending (of which Medicare and Medicaid are the largest parts) accounted in 1995 for more than half of hospital revenues²⁵ and more than twenty-five percent of physician revenues.²⁶

II. “ . . . CALLS THE TUNE ”

The steady growth of the federal budget for health care goods and services, and the corresponding dependence of hospitals and physicians on federal dollars, has given the federal government enormous leverage in its dealings with health care providers. The Department of Health and Human Services (DHHS), which administers the Medicare and Medicaid programs through the Health Care Financing Administration (HCFA), has used its leverage to be a more prudent purchaser of goods and services, especially in the last fifteen years. In addition, Congress has been able to impose reforms on the health care industry by exercising its Taxing and Spending Clause²⁷ powers to make compliance with those reforms part of the terms and conditions of participation in the Medicare and Medicaid programs. Some of the major changes brought about by Congress' twin roles— informed purchaser and industry reformer—are described in the remainder of this section.

A. *Universal Single-Payer Health Care Insurance (for Seniors)*

Despite the demise of the Clinton health care reform plan in the early 1990's, and against the backdrop of continued pleas for and against a single-payer system for the United States, Congress has effectively placed most senior citizens into a single-payer system, at least with respect to the benefits covered by Medicare. Congress accomplished this by tinkering with its initial promise not to interfere with beneficiaries' freedom of

25. See MEDICARE CHARTBOOK, *supra* note 11, at 20, Table 1.10.

26. *Id.* at 26, Table 1.13.

27. See U.S. CONST. art. I, § 8, cl. 1. Unlike the Commerce Clause, *id.* cl.3, which has recently suffered a few setbacks, *e.g.*, *United States v. Morrison*, 120 S. Ct. 1740 (2000) (Congress lacks authority under Commerce Clause to enact civil remedy provisions in the Violence Against Women Act), the Taxing and Spending Clause continues to be a robust, if not quite unlimited, source of legislative power. See, *e.g.*, *New York v. United States*, 505 U.S. 144, 166-67 (1992) (even though Congress may not directly compel state legislative or regulatory action, it may induce that action by placing conditions on the receipt of federal funds); *South Dakota v. Dole*, 483 U.S. 203, 211 (1987) (condition must relate to the purpose behind the expenditure of federal money); *Pennhurst State School & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981) (conditions must be expressly stated). Presumably Congress' ability to impose conditions on the receipt of federal funds by private entities is even less constrained. *Cf. Steward Mach. Co. v. Davis*, 301 U.S. 548, 589, 590 (1937) (emphasizing that a private entity, not a state, was the challenging party).

choice of provider.²⁸ In 1997 Congress amended the Medicare statute and effectively prevented most physicians from entering into private contracts with most Medicare beneficiaries for most, if not all, covered services.²⁹ The result is that physicians and their patients must look to the Medicare program for payment for services that are covered by the program and may not arrange for payment outside the system. Thus, within the ambit of services covered by Medicare, Congress has created a single-payer system and has locked into that system the seniors who are the direct beneficiaries of the program and their children and other potential heirs who are (to the same extent) relieved of the financial burden of paying for health care for those seniors. It will be interesting to see what effect Congress' gambit of locking beneficiaries and their physicians into the program will have on the political dynamics of the program in the years ahead.

B. Challenging the Culture of Hospitals and their Medical Staffs

In response to high inflation in the hospital industry, a mushrooming Medicare budget, a growing federal budget deficit, and initiatives by the Reagan Administration, Congress in 1983 changed the way hospitals were paid for in-patient services from a cost-based system to a prospective payment system (PPS).³⁰ Under PPS, in-patient services are paid in an amount that is established in advance. Although some provision is made to reimburse hospitals for very expensive "outliers," a certain amount of variation in costs is expected from patient to patient, but the amount Medicare pays remains fixed.³¹ The idea behind PPS³² is that it creates an

28. See *supra* note 13 and accompanying text.

29. Congress did not actually prohibit private contracts, but the conditions it imposed are so onerous, most physicians simply cannot afford to use them. If a physician chooses to enter into a private contract with a Medicare beneficiary, the physician must at the same time promise not to bill the Medicare program for *any* services provided to *any* Medicare beneficiary (not just the beneficiary on the other side of the private contract) for a period of two years. See 42 U.S.C. § 1395a(b)(3) (Supp. III 1997). If the physician nonetheless "knowingly and willfully" breaches the promise and submits a claim during the two-year period, the physician may accept no payments of any kind for any services provided to any Medicare beneficiaries for the remainder of the two years. See *id.* § 1395a(b)(3)(C).

30. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(c)(1), 97 Stat. 65 (1983) (codified as amended at 42 U.S.C. § 1395ww (1994)). The history and impact of PPS are reviewed in Eleanor D. Kinney, *Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program*, 19 IND. L. REV. 1151, 1158-71 (1986).

31. See e.g. Kinney, *supra* note 30 at 1176.

32. There appears to have been not one idea, but many, behind the adoption of PPS, and the rationales and goals, argues Professor David Frankford, were somewhat contradictory and incomplete. See David M. Frankford, *The Medicare DRGs: Efficiency and Organizational Rationality*, 10 YALE J. ON REG. 273 (1993).

incentive for hospitals to provide more efficient, cost-effective care, because they are penalized financially when costs exceed the PPS payment and are rewarded when their costs fall below the PPS payment. One of the problems that PPS apparently did not anticipate and has not solved is that hospitals, who have good reason to economize on patient care, do not have direct control over the physician-centered decision making process that largely determines the utilization of resources for patient care. Moreover, Medicare's payment methodology for physicians has remained essentially fee-for-service, so that the system's financial incentives for physicians run against its financial incentives for hospitals.

The tension between hospital administrators and physicians over "practice styles" and patient decision making was not created by Medicare. The "corporatization" of hospital management, the disappearance of the charitable immunity doctrine, and the hospitals' increased legal exposure under theories of vicarious liability and corporate negligence have all contributed to a climate in which hospitals jockey with medical staffs for *de facto* control of the medical care provided within their walls. Medicare's shift to PPS, however, has added financial concerns to what had already become a difficult political situation.

C. New Technologies

HCFA is prohibited from paying for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."³³ One way HCFA can carry out its obligations under this provision of law is by making "national coverage decisions," which grant, limit, or exclude Medicare coverage for specific medical services, procedures, and devices.³⁴ The impact of this activity on access to health care goods and services is obvious and immediate and has the potential to slow down the dissemination of new technologies, although national coverage denials are far outnumbered by local coverage determinations.³⁵ National coverage determinations have a second effect, as well: "When a manufacturer considers bringing a new drug, medical device, or biologic to market, two fundamental questions are who will use it and who will pay for it."³⁶ For

33. 42 U.S.C. § 1395y (1994).

34. This process is described in Criteria for Making Coverage Decisions, 65 Fed. Reg. 31124 (2000) (notice of intent to publish a proposed rule).

35. See FURROW ET AL., *supra* note 22, at 546.

36. John B. Reiss, *Commentary on Payment and Reimbursement Issues Affecting the Marketing of Drugs, Medical Devices, and Biologics, with Emphasis on the Anti-Kickback Statute and Stark II*, 52 FOOD & DRUG L.J. 99, 99 (1997).

drugs and devices that “will be used primarily by the aged population, the major concern is Medicare’s coverage and payment regulations[,] . . . which tend to set the standard for other payors.”³⁷ National coverage decisions, therefore, have the potential to affect manufacturers’ decisions about bringing new products to market and even where to invest their research-and-development dollars.³⁸

D. Restructuring the Industry

As a smart purchaser of health care goods and services, HCFA has a strong interest in not getting ripped off. Even a small percentage of waste or fraud, multiplied times the huge Medicare budget, can be billions and billions of dollars—after a while, as Everett Dirksen was fond of saying, you could be talking about real money.³⁹ Congress has attempted to deal with fraud and abuse of the Medicare program through legislation that has been implemented by HCFA and by DHHS’ Office of Inspector General (OIG). Much of the anti-fraud legislation deals with garden-variety fraud—*e.g.*, billing for services that were not rendered, double-billing for services that were, misdescribing the services rendered in order to increase reimbursements.⁴⁰

Two other provisions, however, do not address ordinary fraud at all. The first, commonly known as the anti-kickback law, prohibits the payment (or offer) or receipt (or solicitation) of “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind” in return for (or to induce) the referral of a patient (or the ordering, leasing, purchasing, etc. of goods, facilities, services, etc.) and for which the Medicare (or Medicaid) program may pay.⁴¹ The second provision, usually referred to as Stark II (in honor of its sponsor, Representative Pete Stark), broadly prohibits self-referrals by physicians—that is, referrals to entities in which the physician has an investment interest

37. *Id.*

38. See generally David M. Frankford, *Food Allergy and the Health Care Financing Administration: A Story of Rage*, 1 WID. L. SYMP. J. 159 (1996); Richard A. Rettig, *Artificial Kidneys and Artificial Hearts*, 65 S. CAL. L. REV. 503 (1991); Note, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095 (1992).

39. RESPECTFULLY QUOTED 155 (Suzy Platt, ed. 1989) (attributing quotation to Sen. Dirksen but noting its absence from formal addresses and papers of the senator).

40. These types of activities and others like them are addressed in 42 U.S.C.A. §§ 1320a-7 (providing for exclusion from the program for prohibited acts), 1320a-7a (civil monetary penalties), 1320a-7b (criminal penalties), 1320a-7c to 7e (providing for elements of fraud and abuse control program, advisory opinions and fraud alerts, and fraud and abuse data collection program) (West Supp. 2000).

41. *Id.* § 1320a-7b(b).

or a compensation arrangement.⁴²

Both of these laws are aimed at program "abuse" (conduct that may create an incentive to provide unnecessary goods or services), and both laws also arguably promote patient autonomy, by making referrals more a matter of patient choice than one of barter in the marketplace.⁴³ Both laws are also arguably over-inclusive and a hindrance to the development of a rational, efficient marketplace for health care goods and services.⁴⁴ This is not the Essay for a resolution of this debate. What should be noted, however, and what is not even fairly debatable, are the wide-ranging effects both laws have had upon the organization and financing of health care providers and upon the development of a health-law specialty within the bar.

The breadth of the fraud and abuse provisions is truly impressive. Every lease of equipment or office space between a health care provider and potential source of referrals, every medical directorship, every physician group practice, every new financing arrangement, every contract with a billing and collecting firm, every ambulance restocking agreement, every training program, and many other arrangements too numerous to list here requires a consideration of these laws. Often, deals must be restructured, and occasionally they must be abandoned, because of these laws. Their requirements and prohibitions have literally remade the face of the health care industry, since compliance with Medicare fraud and abuse laws is not optional for most physicians, hospitals, home health agencies, nursing homes, and other providers of health care goods and services. The net effect of these changes may be good or bad, but they are real. Those effects will not disappear overnight, even if the federal fraud and abuse laws were repealed, because many states have enacted their own versions of the kickback and the self-referral prohibitions.⁴⁵

The scope and complexity of the statutes and their application to health care providers have spawned dozens of safe harbors,⁴⁶ advisory

42. *Id.* § 1395nn.

43. *See, e.g.,* Timothy Stoltzfus Jost & Sharon Davies, *The Fraud and Abuse Statute: Rationalizing or Rationalization?*, 15 HEALTH AFF. 129 (Winter 1996).

44. *See, e.g.,* James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, *id.* at 118.

45. *See* THOMAS WM. MAYO, NAT'L HEALTH LAWYERS ASS'N, STATE ILLEGAL-REMUNERATION AND SELF-REFERRAL LAWS (1996) (monograph on file with author).

46. *See* 42 C.F.R. § 1001.952 (1999). *See also* Ambulance Restocking Safe Harbor Under the Anti-Kickback Statute, 65 Fed. Reg. 32060 (2000) (notice of proposed rulemaking); Civil Money Penalty Safe Harbor to Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries, 65 Fed. Reg. 25460 (2000) (notice of proposed rulemaking); Clarification of the Initial OIG Safe Harbor

opinions,⁴⁷ fraud alerts,⁴⁸ and “special fraud alerts,” “Medicare advisory bulletins,” and “special advisory bulletins,”⁴⁹ not to mention numerous other forms of explanation, warning, and clarification. Any regulatory scheme that attempted to create a payment system for such a complex human activity as health care is going to replicate that complexity in its own rules. Any health care provider who tries to navigate these waters without the assistance of competent health care counsel, or at least a sophisticated compliance advisor, runs a substantial risk of a costly misstep—and thus was the health law consulting industry born. Beyond advising clients on compliance matters, the health law bar brings and defends against False Claims Act suits by *qui tam* relators,⁵⁰ writes and enforces state and federal regulations, and performs the myriad of functions required by any thoroughly regulated industry. Without the massively complex Medicare and Medicaid statutes and their regulatory kin, health law would likely be a mostly administrative-law practice that revolved around licensure issues, with the occasional risk management, corporate governance, tax compliance, or antitrust question thrown in for some variety.

Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518 (1999) (final rule); Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63504 (1999) (interim final rule with request for comment). Although not technically a “safe harbor” rule, the Stark I regulations, 42 C.F.R. §§ 411.350-.361 (1999), and the proposed Stark II rule, Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659 (1998) (to be codified at 42 C.F.R. parts 411, 424, 435, and 455), accomplish somewhat the same purpose. The Stark law contains far more (and more explicit) exceptions than does the anti-kickback statute, which contains very broad and general prohibitions and directs DHHS to carve out exceptions through the safe-harbor process. For all of its detail, however, the Stark law desperately needs the explanations and clarifications of a legislative rule.

47. The OIG collected its 42 advisory opinions. See Office of Inspector Gen., Dep’t of Health and Human Servs., *Advisory Opinions*, (last modified June 12, 2000) <<http://www.hhs.gov/progorg/oig/advopn/index.htm>>.

48. Fraud alerts were issued in 1996 and 1997 to identify fraudulent scams or schemes that may produce significant dollar losses to the Medicare program or that may pose a threat to patient health or safety. They are collected on the HCFA’s web site. See Health Care Financing Administration, *Listing of Medicare Fraud Alerts*, (last modified Feb. 23, 1998) <<http://www.hcfa.gov/medicare/fraud/UMFA2.HTM>>.

49. These advisories are directed to beneficiaries and providers alike, are primarily intended to heighten awareness of basic fraud and abuse principles, and often include contact information if the reader has knowledge of apparent fraud or abuse. They are collected on the OIG’s web site, Office of Inspector Gen., Dep’t of Health and Human Servs., *Special Fraud Alerts, Medicare Advisory Bulletins and Special Advisory Bulletins* (last modified Feb. 22, 2000) <<http://www.hhs.gov/progorg/oig/frdalrt/index.htm>>, and are published in the Federal Register.

50. See 31 U.S.C. § 3729 (1994).

E. Reforming the Industry

In order to be eligible Medicare payments, hospitals, physicians, and various other health care providers must file provider agreements with DHHS⁵¹ and meet certain other “conditions of participation.”⁵² Many of the elements of these provider agreements are just what one would expect: providers promise to charge only amounts permitted by law, to engage in peer review, to inform Medicare beneficiaries of their rights under the program, and the like. In addition to these strictly program-related items, Congress has leveraged the industry’s reliance on federal dollars to encourage behaviors that are often unrelated to the Medicare program at all. The technique is well known: pursuant to its taxing and spending powers, Congress can attach conditions to the receipt of federal funds as long as the conditions are stated explicitly and there is some minimal relationship between the object of the expenditure and the condition established by Congress.⁵³ By attaching conditions to the receipt of Medicare funds, Congress has been able to influence provider behaviors beyond what was strictly necessary to accomplish the goals of the Medicare program and to extend its influence into disparate areas of health law. Consider these examples:

1. Anti-dumping

The provider agreement obligates hospitals to comply with the Emergency Medical Treatment and Active Labor Act⁵⁴ (EMTALA), often referred to as the “anti-dumping law.”⁵⁵ This law obligates hospitals to provide a medically appropriate screening of any person who comes to the emergency department⁵⁶ and, if the person has an emergency medical condition, to stabilize the medical condition (within the hospital’s ability to

51. 42 U.S.C.A. § 1395cc (West. Supp. 2000).

52. As used in this Essay, “conditions of participation,” which apply to hospitals paid under Part A of the Medicare statute, also include “conditions of coverage,” which are applicable to various providers paid pursuant to Part B of the statute. See generally FURROW ET AL., *supra* note 22, at 550-51.

53. See *supra* note 27 and accompanying text.

54. 42 U.S.C. § 1395dd (1994).

55. Actually, the provider agreement is somewhat redundant, since hospitals are obligated to comply with EMTALA, which was enacted in 1986 as an amendment to the Medicare statute, whether or not they are participating hospitals. Compare *id.* § 1395dd(a)-(c) (describing obligations of “hospital”) with *id.* §§ 1395dd(d) (subjecting a “participating hospital” that violates EMTALA to civil money penalties) & 1395dd(e)(2) (defining “participating hospital” as one that has executed a provider agreement pursuant to *id.* § 1395cc).

56. *Id.* § 1395dd(a).

do so) or to transfer the patient to an appropriate facility.⁵⁷ EMTALA is a salutary attempt to eliminate the scandalous practice of “dumping” patients who could not pay for their care on public hospitals, sometimes delaying the life- or limb-saving treatment necessary to meet the patient’s medical needs.⁵⁸ It is not limited, however, to Medicare beneficiaries who come to the hospital’s emergency department; the hospital’s duties extend to any person regardless of that person’s status as a Medicare beneficiary.⁵⁹ In one well-known case, for example, the United States Court of Appeals for the Fourth Circuit held that EMTALA extends to an anencephalic infant who repeatedly came to a Virginia hospital’s emergency room in respiratory distress.⁶⁰

2. *Organ donation*

Because of a critical shortage of organs for transplant, thousands of organ transplant candidates die each year while waiting for an organ.⁶¹ To help increase the rate of organ donation, one of the Medicare conditions of participation for hospitals requires hospitals to inform the local organ procurement organization when a patient’s death is imminent or has occurred and to “[e]nsure . . . that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate.”⁶²

3. *Advance directives*

All fifty states recognize, by statute or by court decision, “living wills,” and many states recognize medical powers of attorney, out-of-hospital do-not-resuscitate orders, and other directives for advance end-of-life decision making. In 1990, Congress enacted the Patient Self-Determination Act,⁶³ which required hospitals and other institutional health care providers to inform patients of their rights under state law, and to

57. *Id.* § 1395dd(b)(1). The transfer itself must satisfy certain detailed requirements and must be “appropriate.” *Id.* § 1395dd(c).

58. See Brian E. Kamoie, *EMTALA: Reaching Beyond the Emergency Room to Expand Hospital Liability*, 33 J. HOSP. L. 25, 26 (Winter 2000).

59. See e.g., 42 U.S.C. § 1395dd(a), (b)(1) (1994).

60. See *In re Baby K*, 16 F.3d 590 (4th Cir.), *cert. denied*, 513 U.S. 825 (1994).

61. See INSTITUTE OF MEDICINE, ORGAN PROCUREMENT & TRANSPLANTATION 61-82 (1999).

62. 42 C.F.R. § 482.45(a)(3) (1999).

63. The Patient Self-Determination Act was introduced as S. 1766, 101st Cong. (1989) and eventually enacted as part of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §§ 4206, 4751, 104 Stat. 1388, 1388-115 to -117, 1388-204 to -206 (codified in scattered sections of 42 U.S.C.).

formulate institutional policies for dealing with advance directives.⁶⁴ Compliance with the Patient Self-Determination Act is included in the provider agreement signed by hospitals, skilled nursing facilities, nursing facilities, home health agencies, and hospices.⁶⁵

4. *Patients' Rights*

A hospital condition of participation requires hospitals to inform all patients of their rights, and to protect the exercise of those rights, with respect to grievance procedures, privacy and safety, confidentiality, participation in medical decision making, and the use of restraints.⁶⁶

F. *"Spillover" effect on other agencies*

A last example of the pervasive impact of the Medicare program upon health law involves the Internal Revenue Service's approval of tax-exempt health care entities. In February 1999, word got out that the IRS had issued an unpublished private letter ruling approving two exempt hospitals' gainsharing activities.⁶⁷ "Gainsharing" occurs when an entity, such as a hospital, rewards physicians or physician groups for delivering cost-effective care by sharing the savings with the physicians. If the hospital is tax-exempt, it was feared that such an arrangement might constitute excess private benefit or inurement (payment of a benefit to an insider), which could result in monetary penalties or loss of the hospital's tax-exempt status. The IRS, however, ruled that under the right circumstances and with appropriate safeguards, gainsharing was not a threat to the hospitals' tax-exempt status.

Then in July 1999, in a "special advisory bulletin" that also addressed gainsharing,⁶⁸ the OIG concluded that gainsharing programs violate the Medicare statute's prohibition against hospital payments that induce physicians to reduce or limit clinical services to patients⁶⁹ and may violate the anti-kickback statute⁷⁰ as well. The IRS' informal response to the OIG's special advisory bulletin suggested that the tax agency would be

64. See, e.g., 42 U.S.C. § 1395cc(f)(1) (1994).

65. See *id.* § 1395cc(a)(1)(Q); 42 C.F.R. §§ 482.13(b)(1)-(3), 489.100-.104 (1999).

66. See 42 C.F.R. § 482.13 (1999).

67. *IRS Approves Gainsharing Programs in Two Unreleased Private Letter Rulings*, 8 Health Law Rep. (BNA) 295 (Feb. 25, 1999).

68. Publication of the OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37985 (1999) (notice).

69. See 42 U.S.C. § 1320a-7a(b)(1) (1994).

70. See *id.* § 1320a-7b(b).

reluctant to approve gainsharing proposals,⁷¹ at least without first running the proposal past the OIG first.⁷²

All told, these examples show just how pervasive the influence of the Medicare program has been, not only with respect to the legal rules that determine the cost, quality, and level of access to care enjoyed by Medicare beneficiaries, but with respect to the care enjoyed by non-Medicare beneficiaries and even the wholly distinct legal rules administered by a different federal agency.

CONCLUSION

When Volume 1 of the *Syracuse Law Review* appeared in 1949, it initiated what has proved to be a fifty-year (and counting) tradition of excellence. That volume included lead articles by distinguished faculty (Professors Kharas and Miller), legal scholars from other institutions (Julius Cohen, Jerome Frank, and Roscoe Pound), and a couple of government officials (almost-Supreme Court Associate Justice (and Fourth Circuit Judge) John J. Parker and the uninitialed John Edgar Hoover). Judge Alexander Holtzoff of the District Court for the District of Columbia wrote on the thoroughly modern topic (then and now) of fair trial vs. free press.⁷³ Charles Alan Wright, still only a law clerk to Judge Charles E. Clark, co-authored with his judge what may have been his first lead article in a law review;⁷⁴ then, as always, Mr. Wright's prose was tight and his opinions unvarnished.⁷⁵ This was the same year that President Truman urged Congress to enact a national health insurance plan that would be administered by a single federal agency, that would provide for health insurance for the poor through federal grants to the states, that would guarantee freedom of choice of provider, and that would reimburse physicians on either a fee-for-service, capitated, or salary basis, as determined by a majority of practitioners in the individual health service

71. *Government Officials Discuss Gainsharing, IRS 'Reluctant' to Issue Favorable Rulings*, 8 Health L. Rep. (BNA) 1301 (Aug. 5, 1999).

72. *Gainsharing Rulings Requests Sent to IRS Will Likely be Sent to HHS OIG*, 8 Health L. Rep. (BNA) 1776 (Nov. 4, 1999).

73. Alexander Holtzoff, *The Relation Between the Right to a Fair Trial and the Right of Freedom of the Press*, 1 SYRACUSE L. REV. 369 (1950).

74. Charles E. Clark & Charles Alan Wright, *The Judicial Council and the Rule-Making Power: A Dissent and a Protest*, 1 SYRACUSE L. REV. 346 (1950).

75. It's an interesting twist of fate that placed Judge Holtzoff and Charles Alan Wright in the inaugural volume. Holtzoff was co-editor of West Publishing's *magnum opus*, FEDERAL PRACTICE & PROCEDURE (Barron & Holtzoff, eds.), which Professor Wright would begin revising as co-editor in 1960 and which would be succeeded by a completely new edition by Professor Wright (with Arthur Miller and eventually others) a decade later.

areas.⁷⁶ Medicare may have been the most important development to hit health law in fifty years, but a look back to 1949 and through the pages of the first volume of this law review shows that some things haven't changed all that much.

Congratulation to the College of Law and the *Syracuse Law Review* on fifty years of vigorous, helpful legal scholarship and best wishes from a loyal son of Syracuse for another distinguished half-century!

76. See MARMOR, *supra* note 13, at 11-12.